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Programme and Abstracts of the

7th European Multidisciplinary Meeting on Urological Cancers (EMUC)

*Optimising opportunities in multidisciplinary care*

Barcelona, Spain, 12–15 November 2015

In conjunction with
• ESU courses on Medical treatment of metastatic renal cancer and Castrate resistant prostate cancer
• European School of Oncology: Personalised approach to prostate cancer management
• 4th Meeting of the EAU Section of Urological Imaging (ESUI)
• Young Academic Urologists meeting
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**Abstracted/indexed in:** BIOnBASE, EMBASE, Medical Documentation, Current Contents – Clinical Medicine, Science Citation Index, Adis Clinical Trials Insight, SciVerse Scopus®. Full text available on SciVerse ScienceDirect®.

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Printed by Henry Ling Ltd, Dorchester, Dorset, UK
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Welcome to the 7th European Multidisciplinary Meeting on Urological Cancers (EMUC), Barcelona, Spain, 12–15 November 2015

The 7th European Multidisciplinary Meeting on Urological Cancers (EMUC) returns to Barcelona and we are proud to welcome everyone to this annual meeting where standards and best practices in onco-urology treatment are critically assessed and future prospects identified.

We are already in our fifth year of annually organising this meeting and are clearly experiencing the benefits of pushing the envelope of multi-disciplinary strategies. At a time of new discoveries and evolving trends in diagnosis and treatment, the need for collaborative work becomes all the more important, if not crucial.

Through the efforts of the European Society for Medical Oncology (ESMO), the European Society for Radiotherapy & Oncology (ESTRO) and the European Association of Urology (EAU), we have created a reliable platform of professional exchange that enables us to effectively integrate multi-disciplinary initiatives with full attention to the concerns of our patients.

This year the Scientific Programme is complemented by ‘focus meetings.’ The European School of Oncology (ESO) conference will examine “insights on personalised approaches to prostate cancer management”, while the EAU Section of Urological Imaging (ESUI) tackles “Imaging and Individualised Medicine” in its fourth annual meeting.

Courses organised by the European School of Urology (ESU) about “Castrate resistant prostate cancer” and “Medical treatment of metastatic renal cancer”, a meeting of the Young Academic Urologists Working Parties, the ESU/ERUS Hands-on training in Robotic surgery, the Falcon target volume contouring workshop, and Industry Sessions add depth and a practical dimension to EMUC.

We certainly can take as inspiration the legacy of Barcelona, a city known for its diversity and innovative spirit. We encourage all participants to join our faculty members and to actively participate in the discussions as we cast a critical eye on our practices, clinical work and research outcomes.

Welcome to Barcelona for yet another insightful EMUC!

On behalf of the EMUC2015 steering committee:

Prof. Cora Sternberg, Rome (IT)
ESMO Chair

Prof. Philip Poortmans, Nijmegen (NL)
ESTRO President

Prof. Hein van Poppel, Leuven (BE)
EAU Adjunct Secretary-General & Executive Member Education
General Information

Abstracts and Posters
The abstracts are included in this book. Abstracts and posters are available online on www.emuc2015.org.

Accessibility Congress Venue
All sessions during EMUC15 will take place at the Palau de Congressos de Catalunya, which is easily accessible by public transport. The nearest metro stop is Zona Universitaria, a 2 minute walk from the congress venue.
Address:  
Palau de Congressos de Catalunya  
Avda. Diagonal, 661–671  
08028 Barcelona, Spain  
T: +34 93 364 8022  
infopcongresos.com  
www.pcongresos.com

Catering
Coffee breaks and lunches will take place in the exhibition area. The ESUI lunch and the YAU breaks will take place in Hall −1.

Certificate of Attendance

Cloakroom/luggage
A cloakroom is located in the main entrance area and is at participant’s disposal during meeting hours. Be sure to collect all your personal belongings at the end of the day.

Congress Bag
Each delegate can collect a congress bag in the registration area.

Disclosure links to Industry
It is requested that all faculty disclose to the audience any links with the industry related to the topic of their lecture at the beginning of each presentation. A link can be: being a member of the advisory board or having a consulting agreement with a specific company.

Emergency Information
The emergency phone number for police, fire brigade and ambulance service is 112. In case of an emergency in the congress venue contact the security or the organisation immediately. You can also reach the local police by calling 092, the local fire brigade via 080 and for accidents you can call 061.

Electricity
Electricity supply in Barcelona is 220 Volts and the connection is made by a two-pin plug. Please be aware that delegates from the USA will require a voltage converter. Delegates from the United Kingdom will require a plug adapter.

Exhibition
An exhibition will be held jointly with the meeting. EMUC, ESUI, ESO, ESU and YAU will only allow delegates with a “P” on their badge access to industry-sponsored sessions and exhibition stands related to prescription-only medicines. See page xli for more information and profiles of the exhibiting companies.

Exhibition opening hours:
Thursday 12 November 09.00–16.30 hrs  
Friday 13 November 09.00–16.00 hrs  
Saturday 14 November 09.00–16.30 hrs

Insurance
The organisers do not accept responsibility for any personal damage. Participants are strongly recommended to arrange their own personal insurance.

Language
All presentations during the meeting will be conducted in English. No translation will be provided.
Lost and Found
Found items should be returned to the registration desk. If you lose something, please report to this desk for assistance.

Mobile phones
The sound of mobile phones must be switched off during sessions and please do not use flash light.

Poster Builder Service
Poster presenters who created their posters for EMUC15 and ESUI15 through the “Online Poster Builder Service”, can collect their poster at the faculty registration desk in the registration area.

Prayer room
A special room dedicated to prayer is located in room K4 on level −1.

Press
Journalists can obtain free registration to the meeting. All media operators must show their credentials (press card dated 2015/2016 and original assignment letter).

Registration area
The registration area is located at the main entrance.
Opening hours:  
Wednesday 11 November 16.00–18.30  
Thursday 12 November 07.00–18.30  
Friday 13 November 07.00–18.30  
Saturday 14 November 07.30–19.00  
Sunday 15 November 08.00–13.30

Safety
All bags may be subject to inspection. Security is present for your safety. Please take all personal effects with you when leaving the session rooms.

Scientific Posters
The scientific posters are displayed on 12–15 November in the Exhibition Hall. Members of the EMUC Scientific Committee will visit the EMUC poster area to discuss the posters with the presenters according to the following schedule:
Friday 13 November 10.50–11.10  Topic: Prostate Cancer, P001–P020  
Friday 13 November 12.40–13.55  Topic: Prostate Cancer, P021–P070  
Friday 13 November 15.25–16.00  Topic: Prostate Cancer, P071–P097 + P146  
Saturday 14 November 11.40–12.00  Topic: Bladder Cancer, P098–P111  
Saturday 14 November 13.00–14.25  Topic: Bladder Cancer, P112–P139  
Saturday 14 November 16.20–16.50  Topic: Kidney and Testicular, P140–P166
For those who present their poster on Friday you are kindly invited to attend the scientific programme on Saturday when we will announce the best poster at 09.30hrs, in the main auditorium.
For those who present their poster on Saturday you are kindly invited to attend the scientific programme on Sunday. The best poster will be announced at 09.15hrs in the main auditorium.

Smoking Policy
Smoking is prohibited inside the congress venue.

Speaker Service Centre (SSC)
All presentations should be handed in at the Speaker Service Centre (Room Prensa II on level 1), at least three hours prior to the start of the session.
Opening hours:  
Wednesday 11 November 16.00–18.00  
Thursday 12 November 07.00–18.30  
Friday 13 November 07.00–18.00  
Saturday 14 November 07.30–18.45  
Sunday 15 November 08.00–12.30

Transportation
Delegates can collect a complimentary transportation pass in the registration area. The transportation pass is valid during 4 days and can be used for unlimited travel in busses, subways and trams within the city of Barcelona during the meeting.

Tourist Information
For information about Barcelona, you can go to the Barcelona Info desk, or visit www.barcelonaturisme.com/en to find additional information.

Webcasts
All sessions during EMUC15 in Barcelona will be broadcasted via www.emuc2015.org, under the condition that the speaker has given his or her approval.

WI-FI
Free wireless internet will be available in all areas and session rooms. Please search for the “EMUC2015” network and connect by entering the password: EMUC2015.
Floorplan

**Level 0**

**EXHIBITION BOOTHS**
1. Sanofi
2. Siemens
3. Exact Imaging
4. Synergo Medical Enterprises
5. Invivo
6. Olympus
7. Koelis
8. Exelixis
9. Bayer Healthcare
10. Astellas
11. Janssen Pharmaceutical Companies
12. ESTRO
13. ESMO
14. EAU
15. Europa Uomo

**Level -1**

**EXHIBITION BOOTHS**
1. Sanofi
2. Siemens
3. Exact Imaging
4. Synergo Medical Enterprises
5. Invivo
6. Olympus
7. Koelis
8. Exelixis
9. Bayer Healthcare
10. Astellas
11. Janssen Pharmaceutical Companies
12. ESTRO
13. ESMO
14. EAU
15. Europa Uomo

**EXHIBITION BOOTHS**

- E4-5-6 HOT Mimic
- E1-2-3 Falcon

**Meeting Rooms**

- K4 Prayer Room
- K3 Meeting Room
- K2 Meeting Room
- K1 Meeting Room

**To Fairmont Rey Juan Carlos Hotel**
Organisers

**EMUC 2015 Steering Committee**

ESMO         Prof. Cora Sternberg, Rome (IT)
ESTRO        Prof. Philip Poormans, Nijmegen (NL)
EAU          Prof. Hein Van Poppel, Leuven (BE)

**EMUC 2015 Scientific Committee**

ESMO         Dr. Jan Oldenburg, Oslo (NO)
ESMO         Dr. Thomas Powles, London (GB)
ESTRO        Prof. Barbara Jereczek-Fossa, Milan (IT)
ESTRO        Prof. Vincent Khoo, London (GB)
EAU          Prof. Alberto Briganti, Milan (IT)
EAU          Prof. George Thalmann, Berne (CH)
EORTC GUCG  Prof. Bertrand Tombal, Brussels (BE)
EUOG         Prof. Susanne Osanto, Leiden (NL)
ESUR         Prof. Gertraud Heinz-Peer, St. Poelten (AT)
ESUR         Prof. Harriet Thoeny, Berne (CH)
ESP/ESUP     Prof. Antonio Lopez-Beltran, Lisbon (PT)
ESUI         Dr. Jochen Walz, Marseille (FR)
YAU          Dr. Francesco Sanguedolce, London (GB)

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www.emuc2015.org
UPCOMING CONFERENCES

- Molecular Analysis for Personalised Therapy-MAP
  In partnership with Unicancer and CRUK
  Paris, France – 23-24 October 2015

- ESMO Summit Americas – Oncology updates: From evidence to practice
  Miami, Florida, USA – 6-8 November 2015

- European Multidisciplinary Meeting on Urological Cancers – EMUC
  In partnership with EAU and ESTRO
  Barcelona, Spain – 12-15 November 2015

- ESMO Symposium on Immuno-Oncology
  Lausanne, Switzerland – 20-21 November 2015

- ESMO Asia 2015 Congress
  Singapore – 18-21 December 2015

- Sarcoma & GIST Conference
  Milan, Italy – 16-17 February 2016

- ESMO Symposium on Signalling Pathways in Cancer
  In partnership with EACR
  Sitges, Spain – 4-5 March 2016

- European Lung Cancer Conference – ELCC
  In partnership with IASLC, ESTRO, ESTS and ETOP
  Geneva, Switzerland – 13-16 April 2016

- IMPAKT Breast Cancer Conference
  In partnership with BIG, EBCCouncil and SONK
  Brussels, Belgium – 12-14 May 2016

- ESMO World Congress on Gastrointestinal Cancer
  Barcelona, Spain – 29 June-2 July 2016

- ESMO Academy

- ESMO 2016 Congress
  Copenhagen, Denmark – 7-11 October 2016

- ESMO Symposium on Immuno-Oncology
  Lausanne, Switzerland – 4-5 November 2016

- ESMO Asia 2016 Congress
  Singapore – 16-19 December 2016

- ESMO 2017 Congress
  In partnership with EACR
  Madrid, Spain – 8-12 September 2017

Reduced registration fees for ESMO members.

A variety of Preceptorships and other Educational Courses are organised throughout the year.
Accreditation

Continuing Medical Education Accreditation EMUC

The ’7th European Multidisciplinary Meeting on Urological cancers (EMUC)’ is accredited by the European Accreditation Council for Continuing Medical Education (EACCME) to provide the following CME activity for medical specialists. The EACCME is an institution of the European Union of Medical Specialists (UEMS), www.uems.net.

The ’7th European Multidisciplinary Meeting on Urological cancers (EMUC)’ is designated for a maximum of (or ‘for up to’) 18 hours of European external CME credits. Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

Through an agreement between the European Union of Medical Specialists and the American Medical Association, physicians may convert EACCME credits to an equivalent number of AMA PRA Category 1 Credits™. Information on the process to convert EACCME credit to AMA credit can be found at www.ama-assn.org/go/internationalcme.

Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME for ECMEC credits are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of The Royal College of Physicians and Surgeons of Canada.

EACCME credits

Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity. The EACCME credit system is based on 1 ECMEC per hour with a maximum of 3 ECMECs for half a day and 6 ECMECs for a full-day event.

The event has also been accredited with 13 ESMO-MORA category 1 credits.

Continuing Medical Education Accreditation ESUI

The ‘4th Meeting of the EAU Section of Urological Imaging (ESUI)’ is accredited by the European Accreditation Council for Continuing Medical Education (EACCME) to provide the following CME activity for medical specialists. The EACCME is an institution of the European Union of Medical Specialists (UEMS), www.uems.net.

The meeting is designated for a maximum of 6 hours of European external CME credits. Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

Through an agreement between the European Union of Medical Specialists and the American Medical Association, physicians may convert EACCME credits to an equivalent number of AMA PRA Category 1 Credits™. Information on the process to convert EACCME credit to AMA credit can be found at www.ama-assn.org/go/internationalcme.

Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME for ECMEC credits are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of The Royal College of Physicians and Surgeons of Canada.

EACCME credits

Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity. The EACCME credit system is based on 1 ECMEC per hour with a maximum of 3 ECMECs for half a day and 6 ECMECs for a full-day event.
EARLY REGISTRATION DEADLINE: 20 JANUARY 2016
Hands-on Training (HOT)

Aims and Objectives
The European School of Urology (ESU) and the EAU Robotic Urology Section (ERUS) offer an intensive hands-on training course. We will provide training using simulators. The main aims of this 90 minutes course are: improving the participants’ control-skills and hand-eye-coordination, as well as an objective benchmarking of console performance and an introduction into standardized surgical steps in robot-assisted procedures. Therefore, each course is limited to the small number of 4 participants, to facilitate an optimal training setting with only 1 participant per tutor.

Course coördinators: Dr. H. Van Der Poel, Amsterdam (NL)  
Prof. A. Mottrie, Aalst (BE)

Tutors: Dr. J. Schraml, Usti Nad Labem (CZ)  
Prof. I. Acar, Ankara (TR)

ROOM E4-5-6  
Friday 13 November 2015
Course 1  08.30 - 10.00
Course 2  11.15 - 12.45
Course 3  13.35 - 15.05
Course 4  15.45 - 17.15

ROOM E4-5-6  
Saturday 14 November 2015
Course 1  08.30 - 10.00
Course 2  11.35 - 13:05
Course 3  14:05 - 15:35
Course 4  16:20 - 17:50
FALCON Workshop

FALCON MRI-based delineation in prostate cancer treatment with focus on focal therapy

Saturday, 14 November from 14:20-16:00
Workshop leaders and panellists: B. De Bar, Lausanne (CH), C. Salembier, Brussels (BE)

Contouring workshop
FALCON workshops have been organised at ESTRO congresses since 2010 and have been growing steadily in popularity. At EMUC 2014 a Hands-on Training (HOT) Prostate radiotherapy delineation contouring workshop was attended by approximately 20 people. At EMUC 2015, ESTRO will offer a FALCON delineation contouring workshop on MRI-based delineation in prostate cancer treatment with focus on focal therapy, as follows.

Target audience
The delineation workshops are aimed at junior clinical or radiation oncologists wanting to improve their contouring skills or more senior specialists wanting to refresh and validate their knowledge and skills in this field.

Structure of the workshops
- Explanation of the contouring software
- Presentation of the clinical case and the delineation exercise
- 30-40 minutes for delineation on site
- Presentation of the delineation guidelines and discussion between experts and participants

FALCON (Fellowship in Anatomic delineation and CONtouring) is the multifunctional ESTRO platform for contouring and delineation. Attending a FALCON workshop offers the opportunity for individual professionals
- to validate their contouring practice during live workshops by comparing them with those from experts and other participants,
- to learn the indications proposed by the experts that coordinate the workshops,
- to discuss with other participants, experts and panelists,
- to communicate and use the delineation guidelines in order to further integrate themselves into daily practice.
Scientific Programme

Thursday 12 November

4th Meeting of the EAU Section of Urological Imaging (ESUI)

Room: H1, level -1

08.30-08.35 Welcome by the ESUI
   J. Walz, Marseille (FR)

08.35-09.00 News from the ESUI
   Chair: J. Walz, Marseille (FR)

08.35-08.40 Results from the ESUI and EAU Guideline Office joint committee
   T. Loch, Flensburg (DE)

08.40-09.00 Standard operating procedures for ultrasound examinations
   Genital organs: Prostate and testis
   P. Martino, Bari (IT)
   Urinary tract: Kidney and bladder
   C. Trombetta, Trieste (IT)

09.00-10.20 Imaging and individualised medicine in urology
   Moderators: P.A. Geavlete, Bucharest (RO)
   M. Ritter, Mannheim (DE)
   H. Thoery, Berne (CH)

09.00-09.15 Bladder cancer staging with MRI: Can we finally stage correctly?
   T. El Diasty, Mansoura (EG)

09.15-09.30 3D vascular anatomy for partial nephrectomy: How to do it and how it improves selective clamping?
   M. Gallucci, Rome (IT)

09.30-09.45 Stone characterisation with imaging and how to fine-tune stone treatment
   M. Ritter, Mannheim (DE)

09.45-10.00 Functional imaging of the kidney and how it helps to individualise management
   M. Notohamiprodjo, Tübingen (DE)

10.00-10.15 NBI, PDD and SPIES in individualised treatment of upper urinary tract urothelial cancer
   O. Traxer, Paris (FR)

10.15-10.20 Questions and answers

10.20-10.50 Coffee break and poster viewing

10.50-11.50 New imaging technologies on the horizon
   Moderators: M. Ferreira Coelho, Lisbon (PT)
   C. Trombetta, Trieste (IT)
   A. Villers, Lille (FR)

10.50-11.00 Radio Immuno Guided Surgery (RIGS) in urology
   S. Siracusano, Trieste (IT)

11.00-11.10 High resolution ultrasound in urology
   C. Pavlovich, Baltimore, Maryland (US)
11.10-11.20 Super-fast ultrasound in urology
M. Tanter, Paris (FR)

11.20-11.30 7T MRI in urology: Are high field strengths ready for practice?
T. Scheenen, Nijmegen (NL)

11.30-11.40 Iron nanoparticles: Are they back on the block?
T. Scheenen, Nijmegen (NL)

11.40-11.50 Questions and answers

11.50-13.00 Lunch / 12.00-13.00 Industry-sponsored symposium

13.00-14.30 Molecular imaging in Urology: Joint sessions of the EAU Section of Urological Imaging (ESUI) and the European Association of Nuclear Medicine (EANM)
Moderators: A. Briganti, Milan (IT)
S. Fantl, Bologna (IT)
J. Walz, Marseille (FR)

13.00-13.25 Point and counterpoint in prostate cancer: Does PET really change the management of prostate cancer?
Yes, it does: R. Schiavina, Bologna (IT)
No, it does not: L. Budäus, Hamburg (DE)

13.25-13.40 Ultrasound and molecular imaging
H. Wijkstra, Amsterdam (NL)

13.40-13.55 The best PET tracer for prostate cancer: FACBC, PSMA, 18F-Choline, 11C-Choline, ...?
S. Fantl, Bologna (IT)

13.55-14.10 Critical assessment of FDG-PET for bladder cancer staging: For the better or for the worse?
L. Mertens, Amsterdam (NL)

14.10-14.25 The sentinel node technique: A dead horse in Urology?
H. Van Der Poel, Amsterdam (NL)

14.25-14.30 Questions and answers

14.30-15.15 Poster session and best poster award
Moderators: P. Martino, Bari (IT)
G. Salomon, Hamburg (DE)

14.30-14.40 Staging and restaging prostate cancer with Ga-68 PSMA PET-CT: Initial results of a contemporary cohort
O. Acar, Istanbul (TR)

14.40-14.50 MRI can reduce the number of prostate biopsies after previous confirmatory biopsy in men on active surveillance for low-grade prostate cancer
A. Alberts, Rotterdam (NL)

14.50-15.00 Targeted dual-modality imaging in renal cell carcinoma: An ex vivo kidney perfusion study
M. Hekman, Nijmegen (NL)

15.00-15.10 Percutaneous 3T MR-guided cryoablation of small renal masses: Initial experience
T. Van Oostenbrugge, Nijmegen (NL)

15.10-15.15 Best poster award

15.15-15.45 Coffee break and poster viewing
15.45-17.50  How can imaging individualise and optimise prostate cancer management?
            T. Loch, Flensburg (DE)
            V. Scattoni, Milan (IT)

15.45-16.10  Point and counterpoint in prostate cancer imaging: MRI detects especially significant 
prostate cancers, myth or truth?
Myth:       J. Walz, Marseille (FR)

16.10-16.20  What is the new standard of prostate MRI? Mandatory sequences and PIRADS 2.0
J. Futterer, Nijmegen (NL)

16.20-16.30  New perspectives of prostate ultrasound: Quantification of contrast enhanced ultrasound
M. Misch, Eindhoven (NL)

16.30-16.40  New perspectives of prostate ultrasound: Quantification with shearwave elastography
G. Salomon, Hamburg (DE)

16.40-16.50  New perspectives of prostate ultrasound: Use of ANNA/C-TRUS for multiparametric 
ultrasound
T. Loch, Flensburg (DE)

16.50-17.00  New perspectives of prostate ultrasound: Do we need an PIRADS score for ultrasound?
A. Postema, Amsterdam (NL)

17.00-17.10  mpMRI of the prostate: Does it change indications for biopsy and repeat biopsy?
V. Scattoni, Milan (IT)

17.10-17.20  Critical assessment of MRI in the local staging of prostate cancer
M. De Rooij, Nijmegen (NL)

17.20-17.30  mpMRI in patients considered for active surveillance for prostate cancer
A. Villers, Lille (FR)

17.30-17.40  Detection of bone metastasis: Is whole body MRI the new reference?
V. Pasoglou, Brussels (BE)

17.40-17.50  Individualised treatment of metastatic prostate cancer: Monitoring of treatment response
A. Padhani, Northwood (GB)

17.50-18.00  Summary and closure of the 4th ESUI Meeting

Thursday, 12 November

European School of Oncology (ESO) Conference: Personalised Approach to Prostate Cancer Management

Room: H2, level -1

08.30-08.35  Welcome
H. Van Poppel, Leuven (BE)
K. Touijer, New York (US)
R. Valdagni, Milan (IT)

08.35-09.05  Invited lecture: Paradigm shifts in prostate cancer
K. Touijer, New York (US)
09.05-09.35 Invited lecture: Androgen-regulated transcription in prostate cancer
F. Claessens, Leuven (BE)

09.35-09.55 Who is at risk? Population screening or individualised prediction?
M. Roobol, Rotterdam (NL)

09.55-10.20 Coffee break

10.20-12.20 Towards prediction in diagnosis
Chairs: C. Moore, London (GB)
        N. Mottet, Saint-Étienne (FR)

10.20-10.40 Genetic/genomic tools
F. Demichelis, Trento (IT)

10.40-11.00 Transcriptome sequencing
G. Jenster, Rotterdam (NL)

11.00-11.20 Biomarkers
A. Bjartell, Malmö (SE)

11.20-11.40 Imaging
C. Moore, London (GB)

11.40-12.00 Molecular imaging
U. Haberkorn, Heidelberg (DE)

12.00-12.20 Discussion

12.20-13.20 Lunch break

13.20-14.40 Personalising healthcare
Chairs: K. Touijer, New York (US)
        R. Valdagni, Milan (IT)

13.20-13.40 The single patient's needs: Coping with cancer and decision making
L. Bellardita, Milan (IT)

13.40-14.00 The single patient's needs: Life expectancy and comorbidities
A. Vickers, New York (US)

14.00-14.20 The patient's perspective
K. Mastris, Clayhall Iford (GB)

14.20-14.40 Discussion

14.40-17.15 Making cancer treatment personal
Chairs: A. Bossi, Villejuif (FR)
        M. Roobol, Rotterdam (NL)
        C.N. Sternberg, Rome (IT)
        H. Van Poppel, Leuven (BE)

14.40-15.00 What do we need in active surveillance?
R. Valdagni, Milan (IT)

15.00-15.20 What do we need in surgery?
A. Brigantti, Milan (IT)

15.20-15.40 What do we need in radiotherapy?
A. Bossi, Villejuif (FR)

15.40-16.00 Coffee break
16.00-16.20  What do we need in advanced disease?
C.N. Sternberg, Rome (IT)

16.20-16.40  What do we need to identify in patients who may benefit from adjuvant treatments, targeted therapies and drug sequencing combinations?
R.J. Kames, Rochester (US)

16.40-17.00  What do we need about quality of life in long-term survivors?
F. Mols, Tilburg (NL)

17.00-17.15  Discussion

17.15-17.45  Rapid learning systems: Transforming cancer care through Big Data
P. Boyle, Lyon (FR)

17.45-17.55  Conclusions

Thursday 12 November

ESU course on Castrate resistant prostate cancer

Room: A, level -1

14.00-14.05  European School of Urology: A unique possibility for urological education
N. Mottet, Saint-Etienne (FR)

14.05-14.20  Guidelines recommendations EAU, ESMO, NCCN on prostate cancer
N. Mottet, Saint-Etienne (FR)

14.20-14.45  Second line hormonal manipulations in CRPC: Role of enzalutamide and abiraterone
N. Mottet, Saint-Etienne (FR)

14.45-15.10  Bone protective agents in CRPC, role of bisphosphonates and RANKL inhibitors
K. Fizazi, Villejuif (FR)

15.10-15.30  Break

15.30-15.55  Chemotherapeutic options in first and second line
S. Gillesen, St. Gallen (CH)

15.55-16.20  Role of vaccination, immunotherapy and radionuclides in CRPC
N. Mottet, Saint-Etienne (FR)

16.20-17.00  Interactive case discussion
K. Fizazi, Villejuif (FR)
S. Gillesen, St. Gallen (CH)
N. Mottet, Saint-Etienne (FR)

ESU course on Medical treatment of metastatic renal cancer

Room: B1-2-3, level -1

14.00-14.05  European School of Urology: A unique possibility for urological education
M. Kuczyk, Hanover (DE)
14.05-14.20 Guidelines recommendations EAU, ESMO, NCCN on renal cancer  
L. Albiges, Villejuif (FR)

14.20-14.45 When to start with first-line treatment and is there a first choice agent?  
L. Albiges, Villejuif (FR)

14.45-15.10 The role of cytotherapeutic nephrectomy in the era of targeted therapy  
M. Kuczyk, Hanover (DE)

15.10-15.30 Break

15.30-15.55 How to define the optimal sequential treatment after failure of first-line therapy?  
L. Albiges, Villejuif (FR)

15.55-16.20 The efficacy of metastasectomy in metastatic renal cell cancer  
M. Kuczyk, Hanover (DE)

16.20-17.00 Interactive case discussion  
L. Albiges, Villejuif (FR)  
M. Kuczyk, Hanover (DE)

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Friday, 13 November

7th European Multidisciplinary Meeting on Urological Cancers (EMUC)

Room: Auditorium, level 0

08.15-08.25 Welcome and introduction  
Medical oncologist: C. Sternberg (ESMO)  
Radiation oncologist: P. Poortmans (ESTRO)  
Urologist: H. Van Poppel (EAU)  
Radiologist: H. Thoeny (ESUR)  
Pathologist: A. Lopez-Beltran (ESP/ESUP)

08.25-10.50 What’s new in prostate cancer? From epidemiology to genomics  
Chairs: Medical oncologist: T. Powles, London (GB)  
Radiation oncologist: M. Bolla, Grenoble (FR)  
Urologist: R. Karnes, Rochester (US)

08.25-08.45 Global patterns of prostate cancer  
Epidemiologist – A. Jemal, Atlanta (US)

08.45-09.05 Is the Gleason score outdated? The new prognostic grading system  
Pathologist – R. Montironi, Torente di Ancona (IT)

09.05-09.25 Use of MRI-guided biopsy: A real step forward?  
Urologist – C. Moore, London (GB)

09.25-09.45 Genomics: When and for whom  
Urologist – J. Catto, Sheffield (GB)

09.45-10.20 Clinical case discussion on “locally advanced” prostate cancer  
Case presenter: Urologist: F. Chun, Hamburg (DE)  
Medical oncologist: C. Massard, Villejuif (FR)  
Radiation oncologist: P. Ost, Ghent (BE)  
Radiologist: H. Thoeny, Berne (CH)  
Urologist: K. Touijer, New York (US)
10.20-10.40 State of the art lecture: Next generation pathology: Predicting clinical course and targeting disease causation
Chair: Medical oncologist C. N. Sternberg, Rome (IT)
Speaker: Pathologist C. Cordon-Cardo, New York (US)

10.40-10.50 Ra 223: From clinical data to real live practice
Oncologist – J. Carles, Barcelona (ES)

10.50-11.10 Coffee break and poster viewing

11.10-12.40 Prostate cancer in the young patient
Chairs: Medical oncologist S. Osanto, Leiden (NL)
Radiation oncologist R. Valdagni, Milan (IT)
Urologist A. Briganti, Milan (IT)

11.10-11.25 Biomarkers at young age: PSA and beyond
Biostatistician – A. Vickers, New York (US)

11.25-11.40 The role of screening in younger patients
Urologist – M. Roobol, Rotterdam (NL)

11.40-11.55 Is active surveillance too risky in young men?
Urologist – L. Bokhorst, Rotterdam (NL)

11.55-12.10 The perfect curative treatment at long term: What can we achieve?
Urologist – R. Karnes, Rochester (US)

12.10-12.25 Long-term survivorship and quality of life after curative treatment
Medical psychologist – F. Mols, Tilburg (NL)

12.25-12.40 Update on clinical trials in prostate cancer
Chair: Urologist – F. Chun, Hamburg (DE)
Speaker: Urologist – P. Ghadjar, Berlin (DE)


13.55-14.10 Best of journals: Medical oncology
Chairs: Medical oncologist A. Necchi, Milan (IT)
Medical oncologist J. Oldenburg, Oslo (NO)

14.10-15.25 Metastatic kidney cancer
Chairs: Radiation oncologist G. De Meerleer, Ghent (BE)
Urologist M. Kuczyk, Hanover (DE)
Medical oncologist S. Osanto, Leiden (NL)

14.10-14.25 Intratumoral heterogeneity in kidney cancer
Clinician scientist – S. Turajlic, London (GB)

14.25-15.25 Clinical case discussion on metastatic RCC
Case presenter: Urologist A. Volpe, Novara (IT)
Discussants: Radiologist G. Heinz-Peer, Saint Poelten (AT)
Pathologist F. Algba, Barcelona (ES)
Medical oncologist L. Albiges, Villejuif (FR)
Urologist V. Matveev, Moscow (RU)
Radiotherapist C. Cozzarini, Milan (IT)

15.25-16.00 Coffee break and poster viewing

16.00-16.40 Update on systemic treatments in bladder cancer
Chairs: Clinical oncologist R. Huddart, Sutton (GB)
Urologist H. Van Poppel, Leuven (BE)
16.00-16.10 Peri-operative chemotherapy
Medical oncologist – C.N. Sternberg, Rome (IT)

16.10-16.20 Targeted therapies
Medical oncologist – M. De Santis, Coventry (GB)

16.20-16.30 Immune therapy
Medical oncologist – T. Powles, London (GB)

16.30-16.40 Discussion

16.40-17.20 Testis cancer session
Chairs: Urologist N. Mottet, Saint-Étienne (FR)
Medical oncologist A. Necchi, Milan (IT)

16.40-16.50 Optimal imaging for disease recurrence
Radiologist – M. Bertolotto, Trieste (IT)

16.50-17.00 Management of residual masses after RPLN
Urologist – V. Matveev, Moscow (RU)

17.00-17.10 Report from ICUD
Medical oncologist – J. Oldenburg, Oslo (NO)

17.10-17.20 Discussion

17.30-18.30 Industry-sponsored symposium

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**Saturday, 14 November**

**7th European Multidisciplinary Meeting on Urological Cancers (EMUC)**

Room: Auditorium, level 0

08.50-09.30 Oral presentations of the 6 best abstracts
Chairs: Radiotherapist C. Cozzarini, Milan (IT)
Medical oncologist M. De Santis, Coventry (GB)
Urologist F. Sanguedolce, London (GB)

09.30-09.40 Announcement of the 3 best unmoderated posters
Chairs: Medical oncologist J. Bellmunt, Boston (US)
Urologist J. Walz, Marseille (FR)

09.40-11.40 Bladder cancer: Management of carcinoma in situ
Chairs: Medical oncologist M. Galsky, New York (US)
Urologist P. Gontero, Turin (IT)
Urologist M. Rouprêt, Paris (FR)

09.40-09.55 Update on the genome cancer atlas
Urologist – S. Lerner, Houston (US)

09.55-10.10 Optimal management of carcinoma in situ - The role of Hexvix
Urologist – A. Witjes, Nijmegen (NL)

10.10-10.25 The optimal conservative management for CIS
Urologist – L. Martínez-Piñeiro, Madrid (ES)

10.25-10.40 Pathology features with prognostic implications
Pathologist – E. Compérat, Paris (FR)
10.40-10.55  Biomarkers in non-muscle invasive bladder cancer  
Urologist – M. Ribal, Barcelona (ES)

10.55-11.10  What can we ask to imaging in non-muscle invasive bladder cancer?  
Radiologist – V. Panebianco, Rome (IT)

11.10-11.25  Surgical management: Oncological outcomes and follow-up  
Urologist – C. Stief, Munich (DE)

11.25-11.40  Update on clinical trials in urothelial carcinoma  
Urologist – S. Shariat, Vienna (AT)

11.40-12.00  Coffee break and poster viewing

12.00-13.00  MDT case of patient with muscle invasive bladder cancer with minimal nodal invasion  
Chairs: Medical oncologist J. Bellmunt, Boston (US)  
Radiation oncologist To be confirmed  
Urologist G. Thalmann, Berne (CH)  
Case presenter YAU: Urologist E. Xylinas, Paris (FR)  
Discussants: Radiation oncologist A. Kittie, Oxford (GB)  
Pathologist A. Lopez-Beltran, Lisbon (PT)  
Radiation oncologist L. Moonen, Amsterdam (NL)  
Medical oncologist M. Galsky, New York (US)  
Urologist J. Bedke, Tübingen (DE)

13.00-14.25  Lunch and poster viewing / 13.15-14.15 Industry-sponsored symposium

14.25-14.40  Best of journals: Surgery  
Chairs: Urologist F. Montors, Milan (IT)  
Biostatistician A. Vickers, New York (US)

Chairs: Urologist A. Minervini, Florence (IT)  
Urologist P. Mulders, Nijmegen (NL)  
Medical oncologist T. Powles, London (GB)

14.40-14.50  Vaccine therapies  
Medical oncologist – L. Albiges, Villejuif (FR)

14.50-15.00  Understanding the immunology of advanced RCC: The role of checkpoint inhibitors  
Medical oncologist – D. McDermott, Boston (US)

15.00-15.10  Tumour response assessment  
Urologist – J. Bedke, Tübingen (DE)

15.10-15.20  Update on neo-adjuvant and adjuvant therapies  
Urologist – A. Bex, Amsterdam (NL)

15.20-15.30  Discussion

15.30-16.20  Rare kidney tumour session  
Chairs: Urologist U. Capitano, Milan (IT)  
Pathologist E. Compérat, Paris (FR)  
Urologist M. Hohenfellner, Heidelberg (DE)

15.30-15.40  Can a radiologist influence treatment approach?  
Radiologist – G. Petralia, Milan (IT)

15.40-15.50  Rare tumours  
Medical oncologist – G. Malouf, Paris (FR)
15.50-16.00  Hereditary cancers
Pathologist – G. Martignoni, Verona (IT)

16.00-16.10  Discussion

16.10-16.20  Ongoing clinical trials in kidney cancer
Medical oncologist – S. Osanto, Leiden (NL)

16.20-16.50  Coffee break and poster viewing

16.50-17.10  Best of journals: Radiotherapy
Chairs: Radiation oncologist P. Poortmans, Nijmegen (NL)
Radiation oncologist G. De Meerleer, Ghent (BE)

17.10-17.25  State of the art lecture on genomics/ personalised medicine
Chair: Urologist A. Briganti, Milan (IT)
Speaker: Urologist T. Schlomm, Hamburg (DE)

17.25-18.05  Management of upper urinary tract transitional cell carcinoma
Chairs: Urologist S. Shariat, Vienna (AT)
Urologist J. Walz, Marseille (FR)

17.25-17.35  When is organ sparing allowed?
Urologist – M. Rouprêt, Paris (FR)

17.35-17.45  Role and extent of lymph node dissection during nephroureterectomy
Urologist – M. Brausi, Modena (IT)

17.45-17.55  When and how to use chemotherapy
Clinical oncologist – R. Huddart, Sutton (GB)

17.55-18.05  Discussion

18.15-19.15  Industry-sponsored symposium

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**Sunday, 15 November**

**7th European Multidisciplinary Meeting on Urological Cancers (EMUC)**

**Room: Auditorium, level 0**

09.15-09.25  Announcement 3 best unmoderated posters
Chairs: Radiologist H. Thoeny, Berne (CH)
Urologist B. Tombal, Brussels (BE)

09.25-11.15  Prostate cancer: Oligo-metastatic disease
Chairs: Medical oncologist K. Fizazi, Villejuif (FR)
Clinical oncologist V. Khoo, London (GB)
Urologist F. Montorsi, Milan (IT)

09.25-09.40  When science meets the clinics: The rationale beyond cytoreductive approaches in prostate cancer
Urologist – A. Bjartell, Malmö (SE)

09.40-10.00  Management of oligo-metastatic prostate cancer
Clinical case
Urologist – C. Surcel, Bucharest (RO)
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<th>Time</th>
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<th>Speaker/Institution</th>
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<td>10.00-10.15</td>
<td>Clonal heterogeneity and prostate cancer metastases</td>
<td>Pathologist – M. Haffner, Baltimore (US)</td>
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<td>10.30-10.45</td>
<td>Optimal radiotherapy for imaging detected recurrence</td>
<td>Radiation oncologist – A. Bossi, Villejuif (FR)</td>
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<td>10.45-11.00</td>
<td>Optimising hormonal manipulation</td>
<td>Urologist – B. Tombal, Brussels (BE)</td>
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<td>11.00-11.15</td>
<td>Docetaxel: From the start?</td>
<td>Medical oncologist – K. Fizazi, Villejuif (FR)</td>
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<td>11.15-12.05</td>
<td><strong>Take home messages</strong></td>
<td>Radiologist H. Thoeny, Berne (CH)</td>
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<td>Urologist A. Briganti, Milan (IT)</td>
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<td>Pathologist A. Lopez-Beltran, Lisbon (PT)</td>
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<td>12.05-12.15</td>
<td><strong>Closing remarks</strong></td>
<td>Medical oncologist C. Sternberg (ESMO)</td>
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<td>Radiation oncologist P. Poortmans (ESTRO)</td>
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<td>Urologist H. Van Poppel (EAU)</td>
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**Sunday, 15 November**

**Young Academic Urologists Meeting (YAU)**

Room: A, level -1

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<th>Time</th>
<th>Session</th>
<th>Speaker/Institution</th>
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<tr>
<td>08.30-08.45</td>
<td>YAU: 4 years later</td>
<td>Groups’ overview</td>
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<td>F. Sanguedolce, London (GB)</td>
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<td>08.45-09.00</td>
<td><strong>YAU Board</strong></td>
<td>Sections and YAU: An update</td>
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<td>F. Sanguedolce, London (GB)</td>
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<td>09.00-09.30</td>
<td><strong>EAU Board vision</strong></td>
<td>Exiting strategy</td>
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<td>F. Montorsi, Milan (IT)</td>
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<td>09.30-10.00</td>
<td><strong>European Urology Focus: Is there any opportunity for YAU?</strong></td>
<td>A. Briganti, Milan (IT)</td>
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<td>10.00-10.15</td>
<td><strong>YAU Chairman election</strong></td>
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<td>10.15-10.30</td>
<td><strong>Coffee break</strong></td>
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<td>10.30-16.00</td>
<td><strong>Brainstorming of working groups</strong></td>
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### Faculty Lists

#### ESUI Faculty

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<tr>
<th>Faculty Name</th>
<th>City/State/Country</th>
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<tr>
<td>H.U. Ahmed, London (GB)</td>
<td>C. Pavlovich, Baltimore, Maryland (US)</td>
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<td>A. Briganti, Milan (IT)</td>
<td>A. Postema, Amsterdam (NL)</td>
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<td>L. Budäus, Hamburg (DE)</td>
<td>M. Ritter, Mannheim (DE)</td>
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<td>M. de Rooij, Nijmegen (NL)</td>
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<td>T. El Diasty, Mansoura (EG)</td>
<td>V. Scattoni, Milan (IT)</td>
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<td>S. Fanti, Bologna (IT)</td>
<td>T.W.J. Scheenen, Nijmegen (NL)</td>
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<td>M.X. Ferreira Coelho, Lisbon (PT)</td>
<td>R. Schiavina, Bologna (IT)</td>
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<td>J.J. Futterer, Nijmegen (NL)</td>
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<td>M. Gallucci, Rome (IT)</td>
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<td>L. Mertens, Amsterdam (NL)</td>
<td>H.G. Van Der Poel, Amsterdam (NL)</td>
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<td>M. Mischi, Eindhoven (NL)</td>
<td>T.J. Van Oostenbrugge, Nijmegen (NL)</td>
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<td>M. Notohamiprodjo, Tübingen (DE)</td>
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<td>A. Padhani, Northwood (GB)</td>
<td>J. Walz, Marseille (FR)</td>
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<td>V. Pasogluou, Brussels (BE)</td>
<td>H. Wijkstra, Amsterdam (NL)</td>
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#### ESO Faculty

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<th>Faculty Name</th>
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<tr>
<td>L. Bellardita, Milan (IT)</td>
<td>F. Mols, Tilburg (NL)</td>
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<tr>
<td>A. Bjartell, Malmö (SE)</td>
<td>C. Moore, London (GB)</td>
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<td>A. Bossi, Villejuif (FR)</td>
<td>N. Mottet, Saint-Étienne (FR)</td>
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<td>A. Briganti, Milan (IT)</td>
<td>M. Roobol, Rotterdam (NL)</td>
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<td>F. Claessens, Leuven (BE)</td>
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<tr>
<td>F. Demichelis, Boston (US)</td>
<td>K. Touijer, New York (US)</td>
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<td>U. Haberkorn, Heidelberg (DE)</td>
<td>R. Valdagni, Milan (IT)</td>
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<td>G. Jenster, Rotterdam (NL)</td>
<td>H. Van Poppel, Leuven (BE)</td>
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<tr>
<td>R.J. Karnes, Rochester (US)</td>
<td>A. Vickers, New York (US)</td>
</tr>
<tr>
<td>K. Mastris, Clayhall Ilford (GB)</td>
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#### ESU Faculty

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<tr>
<th>Faculty Name</th>
<th>City/State/Country</th>
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<tr>
<td>L. Albiges, Villejuif (FR)</td>
<td>N. Mottet, Saint-Étienne (FR)</td>
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<tr>
<td>K. Fizazi, Villejuif (FR)</td>
<td>M. Kuczyk, Hanover (DE)</td>
</tr>
<tr>
<td>S. Gillessen, St. Gallen (CH)</td>
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</tbody>
</table>
EMUC Faculty

L. Albiges, Villejuif (FR)  C. Massard, Villejuif (FR)
F. Algaba, Barcelona (SP)  V. Matveev, Moscow (RU)
J. Bedke, Tübingen (DE)  D. McDermott, Boston (US)
J. Bellmunt, Boston (US)  A. Minervini, Florence (IT)
M. Bertolotto, Trieste (IT)  F. Mols, Tilburg (NL)
A. Bex, Amsterdam (NL)  R. Montironi, Torrette di Ancona (IT)
A. Bjartell, Malmö (SE)  F. Montors, Milan (IT)
L. Bokhorst, Rotterdam (NL)  L. Moonen, Amsterdam (NL)
M. Bolla, Grenoble (FR)  C. Moore, London (GB)
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M. Brausi, Modena (IT)  A. Necchi, Milan (IT)
A. Briganti, Milan (IT)  J. Oldenburg, Oslo (NO)
U. Capitanio, Milan (IT)  S. Osanto, Leiden (NL)
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G. De Meerleer, Ghent (BE)  M. Roobol, Rotterdam (NL)
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M. Galsky, New York (US)  T. Schiomm, Hamburg (DE)
P. Ghadjar, Berlin (DE)  S. Shariat, Vienna (AT)
P. Gontero, Turin (IT)  C.N. Sternberg, Rome (IT)
M. Haffner, Baltimore (US)  C. Stief, Munich (DE)
G. Heinz-Peer, St. Poelten (AT)  C. Surcel, Bucharest (RO)
M. Hohenfellner, Heidelberg (DE)  G. Thalmann, Berne (CH)
R. Huddart, Sutton (GB)  H. Thoeny, Berne (CH)
A. Jemal, Atlanta (US)  B. Tombal, Brussels (BE)
S. Joniau, Leuven (BE)  K. Touijer, New York (US)
R.J. Karnes, Rochester (US)  S. Turajlic, London (GB)
V. Khoo, London (GB)  R. Valdagni, Milan (IT)
A. Kiltie, Oxford (GB)  H. Van Poppel, Leuven (BE)
M. Kuczyk, Hanover (DE)  A. Vickers, New York (US)
S. Lerner, Houston (US)  A. Volpe, Torino (IT)
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G. Malouf, Paris (FR)  J. Witjes, Nijmegen (NL)
G. Martignoni, Verona (IT)  E. Xylinas, Paris (FR)
L. Martínez-Piñeiro, Madrid (SP)

YAU Faculty

F. Sanguedolce, London (GB)
F. Montors, Milan (IT)
A. Briganti, Milan (IT)
Register now for the early bird fee: Deadline 15 January 2016
About the European Society for Medical Oncology (ESMO)

ESMO is the leading professional organisation for medical oncology, with the overarching goal of improving outcomes for cancer patients everywhere. We are the society of reference for oncology education and information, and are committed to supporting our members to develop and advance in a fast-evolving professional environment.

Founded in 1975, ESMO has European roots with a global reach: we welcome oncology professionals from around the world. We are a home for all oncology stakeholders, connecting professionals with diverse expertise and experience, and speaking with one voice for our discipline. Our education and information resources support an integrated multi-professional approach to cancer care, from a medical oncology perspective. We seek to erase boundaries in cancer care, whether between countries or specialities, and pursue our mission across oncology, worldwide.

The ESMO community brings together more than 11,000 oncology professionals from over 130 countries. Drawing on 40 years of experience and around 500 expert committee members, ESMO serves its members and the oncology community through:

- Post-graduate oncology education and training
- Career development and leadership training for the next generations of oncologists
- International congresses and workshops to share expertise and best practice, learn about the most up-to-date scientific advances, and connect with colleagues in related disciplines.
- Continuously reviewed, evidence-based standards for cancer care in Europe
- Advocacy and consultation to foster a favourable environment for scientific research

Cancer care is rapidly becoming more integrated and more specialised; whether their field is research, diagnosis, treatment, care, or advocacy, oncology professionals need to both build their specialist knowledge and connect with the best practitioners in other disciplines worldwide. ESMO membership makes this possible.

Please visit eso.org to learn more. Across Oncology. Worldwide.
About the European Society for Radiotherapy and Oncology (ESTRO)

Founded in 1980, the European Society for Radiotherapy and Oncology, ESTRO, is a non-profit, scientific organisation whose role is to foster, in all its aspects, radiation oncology, clinical oncology and related subjects, including physics as applied to radiotherapy, radiation technology and radiobiology.

To fulfill its purpose, ESTRO:
- Develops and promote standards of education in radiotherapy and clinical oncology
- Promotes standards of practice in radiotherapy, clinical oncology and related subjects
- Stimulates the exchange of scientific knowledge in all related fields
- Strengthens the clinical specialty of radiotherapy and clinical oncology in relation to other specialties and professions involved in cancer management
- Encourages co-operation with international, regional and national societies and bodies representing radiotherapy, clinical oncology and related subjects
- Facilitates research and development in radiotherapy, clinical oncology and related subjects.

ESTRO 2016 membership
ESTRO is devoted to advancing the goals of radiation oncology. This includes providing its members with outstanding science and education in order to support them in their career advancement. 2016 ESTRO membership is available and offers numerous services:
- Subscription to the Green Journal;
- Reduced fees for attending ESTRO conferences, teaching courses and joint events;
- Online access to scientific information through DOVE, the e-library;
- Eligibility for grants, awards, working groups, faculties and governance positions;
- And much more.

Individual Membership
Full members:
- Active (95€)
- Supporting Ambassador (250€)
Associate members:
- In Training (75€)
- Affiliate (55€)
- Corporate Representative (55€)
Online registration on www.estro.org.

Institutional Membership
ESTRO offers European institutes the possibility to purchase several individual memberships in a batch (minimum of five) for their members. Not only is this very economical, but it also offers several other advantages. To register, send an email to institutional-membership@estro.org. For more information, please visit www.estro.org/members or send an email to membership@estro.org.

Next ESTRO conference
ESTRO 35
4TH GEC-ESTRO WORKSHOP
29 April – 3 May 2016 | Turin, Italy

Meetings in scientific collaboration
EBCC 10 – EUROPEAN BREAST CANCER CONFERENCE
9–11 March 2016 | Amsterdam, The Netherlands
ELCC – 6TH EUROPEAN LUNG CANCER CONFERENCE
13–16 April 2016 | Geneva, Switzerland
2016 WORLD CONGRESS OF BRACHYTHERAPY
27–29 June 2016 | San Francisco, USA

ESTRO School
The ESTRO School is recognised internationally to provide high-quality education in multidisciplinary oncology and offers a wide range of activities. ESTRO organises live teaching courses. In 2016, 36 courses will be organised mostly in Europe and beyond that will attract at least 3,000 participants. And E-learning tools have been developed in order to extend and coordinate teaching resources worldwide:
- FALCON (Fellowship in Anatomic deLineation and CONtouring): ESTRO’s delineation tool
- DOVE (Dynamic Oncology Virtual ESTRO): e-library giving access to educational and scientific material such as articles, conference abstracts, webcasts, e-posters, slides, contouring cases, guidelines, ..., 
- EAGLE: interactive e-learning modules based on educational material of different formats
### Calendar of the 2016 live teaching courses

<table>
<thead>
<tr>
<th>Venue</th>
<th>Course</th>
<th>Date</th>
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<tbody>
<tr>
<td>Budapest, Hungary</td>
<td>Basic clinical radiobiology</td>
<td>27 Feb – 2 March</td>
</tr>
<tr>
<td>Utrecht, The Netherlands</td>
<td>Dose modelling and verification for external beam radiotherapy</td>
<td>6–10 March</td>
</tr>
<tr>
<td>Florence, Italy</td>
<td>Modern brachytherapy techniques</td>
<td>13–16 March</td>
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<tr>
<td>Krakow, Poland</td>
<td>Particle Therapy</td>
<td>14–18 March</td>
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<tr>
<td>London, United Kingdom</td>
<td>IMRT and other conformal techniques in practice</td>
<td>3–7 April</td>
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<tr>
<td>Toronto, Canada</td>
<td>Image-guided cervix cancer radiotherapy with a special focus on adaptive brachytherapy</td>
<td>4–6 April</td>
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<tr>
<td>Barcelona, Spain</td>
<td>Target volume determination – from imaging to margins</td>
<td>10–13 April</td>
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<tr>
<td>Lisbon, Portugal</td>
<td>ESNM ESTRO/ course on molecular imaging and radiation oncology</td>
<td>19–22 May</td>
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<tr>
<td>Tokyo, Japan</td>
<td>Multidisciplinary management of breast cancer</td>
<td>20–22 May</td>
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<tr>
<td>Istanbul, Turkey</td>
<td>Multidisciplinary management of prostate cancer</td>
<td>22–26 May</td>
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<tr>
<td>Brussels, Belgium</td>
<td>Lower GI: technical and clinical challenges for radiation oncologists</td>
<td>25–27 May</td>
</tr>
<tr>
<td>Brussels, Belgium</td>
<td>Upper GI: technical and clinical challenges for radiation oncologists</td>
<td>28–31 May</td>
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<tr>
<td>Vienna, Austria</td>
<td>Advanced brachytherapy physics</td>
<td>29 May – 1 June</td>
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<tr>
<td>Brussels, Belgium</td>
<td>Brachytherapy for prostate cancer</td>
<td>5–7 June</td>
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<tr>
<td>Athens, Greece</td>
<td>Clinical practice and implementation of image-guided stereotactic body radiotherapy</td>
<td>5–9 June</td>
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<tr>
<td>Porto, Portugal</td>
<td>Evidence based radiation oncology – how to evaluate the scientific evidence and apply it to daily practice</td>
<td>12–17 June</td>
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<tr>
<td>Dublin, Ireland</td>
<td>Advanced skills in modern radiotherapy</td>
<td>19–23 June</td>
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<tr>
<td>Moscow, Russia</td>
<td>Multidisciplinary management of lung cancer</td>
<td>26–28 June</td>
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<tr>
<td>Florence, Italy</td>
<td>Multidisciplinary management of head and neck oncology</td>
<td>26–29 June</td>
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<tr>
<td>Chengdu, China</td>
<td>Basic clinical radiobiology</td>
<td>3–7 July</td>
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<tr>
<td>Vienna, Austria</td>
<td>Haematological malignancies</td>
<td>1–3 September</td>
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<tr>
<td>Brussels, Belgium</td>
<td>Palliative care and Radiotherapy – a course on prognosis, symptom control, re-irradiation, oligometastases</td>
<td>8–10 September</td>
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<tr>
<td>Athens, Greece</td>
<td>Physics for modern radiotherapy (joint course for clinicians and physicists)</td>
<td>11–15 September</td>
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<tr>
<td>Cambridge, UK</td>
<td>Basic treatment planning</td>
<td>9–13 September</td>
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<tr>
<td>Cambridge, UK</td>
<td>Advanced treatment planning</td>
<td>14–18 September</td>
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<tr>
<td>Florence, Italy</td>
<td>Imaging for physicists</td>
<td>18–22 September</td>
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<tr>
<td>Avignon, France</td>
<td>Comprehensive quality management in radiotherapy – Risk Management and Patient Safety</td>
<td>1–4 October</td>
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<tr>
<td>Montpellier, France</td>
<td>Biological basis of personalised radiation oncology</td>
<td>17–20 October</td>
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<tr>
<td>Madrid, Spain</td>
<td>Image guided radiotherapy in clinical practice</td>
<td>23–27 October</td>
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<tr>
<td>Vienna, Austria</td>
<td>Best practice in radiation oncology – A workshop to train RTT trainers in collaboration with the IAEA – Part I</td>
<td>24–28 October</td>
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<tr>
<td>Amsterdam, The Netherlands</td>
<td>ESTRO/ESOR Multidisciplinary approach of cancer imaging</td>
<td>10–12 November</td>
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<tr>
<td>Paris, France</td>
<td>Accelerated breast irradiation</td>
<td>13–16 November</td>
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<tr>
<td>Prague, Czech Republic</td>
<td>4th Masterclass in radiation oncology</td>
<td>19–23 November</td>
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<tr>
<td>Sydney, Australia</td>
<td>Evidence based radiation oncology – How to evaluate the scientific evidence and apply it to daily practice</td>
<td>20–25 November</td>
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<tr>
<td>Bangkok, Thailand</td>
<td>Paediatric radiation oncology</td>
<td>3–5 December</td>
</tr>
<tr>
<td>Pune, India</td>
<td>Advanced technologies</td>
<td>6–10 December</td>
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About the European Association of Urology (EAU)

Founded in 1972, the European Association of Urology (EAU) represents the leading authority within Europe on urological practice, research and education. Over 14,000 medical professionals have joined its ranks and contribute to our mission: To raise the level of urological care throughout Europe and beyond.

With the goal to create a dynamic network, the EAU supports medical professionals active in the field of urology through many of its scientific, professional, educational and awareness-building initiatives:

- **Career Development.** Whether you are a resident, a young urologist or an experienced specialist, the EAU supports urologists throughout their career with programmes for continuing medical education and certification. We offer several educational programmes developed by the European School of Urology (ESU), scholarships and clinical visits. One of the most important tools to continue your professional development is UROsource, the EAU learning library for urologists. With over 50,000 items of scientific content it is the single largest knowledge base available today in the field of urology.

- **Clinical Guidelines.** For any successful clinician, having the most up-to-date evidence-based recommendations on hand is crucial for the successful treatment of your patients. The EAU Guidelines are unparalleled in that regard and used all across the world. They are comprehensively updated on an annual basis and freely accessible for all members.

- **Political Activities.** Urologists are bound by national and, increasingly, international laws that govern treatment options and patient care. The EAU brings together the voices of medical professionals, researchers, innovators and patients on a European platform to keep urological topics on the agendas of the authorities.

- **Networking with Peers.** The EAU offers a wide range of events and courses to interact with the best specialists in the field of urology. The Annual EAU Congress is the largest urology-related event in the world where you can network with like-minded professionals.

- **Advancing Urological Science.** Our journal, European Urology, has been a prestigious urological forum for over 35 years, and is currently read by more than 20,000 urologists. It is one of the most widely-cited medical journals in the world and, with an impact factor of 13.938 leading in its field. Members have free access to full-text articles.

If you are interested in joining the largest international urological community in Europe, please visit www.uroweb.org/membership and find out what other benefits the EAU membership has to offer.
About the European School of Urology (ESU)

The European School of Urology (ESU), on behalf of the EAU Education Office, responds to the education and training needs of urologists. Through various activities, the ESU stimulates, coordinates and organises all post-graduate teaching, education and hands-on training offered by the EAU. With the ESU’s focus on knowledge-sharing and skills development, it provides support to doctors at any stage of their career in urology and to allied medical professionals. To enhance and facilitate the learning experience, the ESU employs both online technology and traditional teaching methods in its courses offered during the Annual EAU Congress and accredited meetings. This makes the ESU a front-line educational resource for professionals in urology. Over 16,000 medical professionals, world-wide, benefit from the ESU’s activities and projects, contributing to forward-looking solutions in medical education and professional growth.

The ESU’s success is anchored on the continued support of the ESU faculty, a community of 150 opinion leaders and experts in various urological specialties. They invest their time and expertise to all teaching activities on a voluntary basis, and we are grateful for their commitment to improve medical education and contribute to the progress of international urology. To learn more about the European School of Urology, visit www.uroweb.org/education or contact the ESU at esu@uroweb.org.

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M. Kuczyk, Hanover (DE)
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L. Martínez-Piñeiro, Madrid (ES) – Ex-Officio
H. Van Poppel, Leuven (BE) – Ex-Officio
About the European School of Oncology (ESO)

The European School of Oncology (ESO) is an independent non-profit organisation established in 1982 by the Italian cancer surgeon, Umberto Veronesi. The School’s mission is to help improve the standards of treatment and care for cancer patients across Europe and “to contribute through education to reducing the number of cancer deaths and to ensuring early diagnosis, optimal treatment, and holistic patient care.”

**Activities**

ESO holds 20–25 courses each year on various cancer types and methods of treatment and care. The School also holds an annual Masterclass in Clinical Oncology and a Masterclass in Oncology Nursing, where participants are selected on a competitive basis. As well as traditional classroom education, ESO also has an online distance learning programme which includes fortnightly e-grandround webcasts and a Master online course in Advanced Oncology which is held together with the University of Ulm. Also in cooperation with the University of Ulm, the **Certificates of Competence** in Lymphoma and in Breast Cancer are organised.

In recent years, ESO has broadened its scope with the inclusion of conferences to its programme such as Advanced Breast Cancer, Active Surveillance for Low-Risk Prostate Cancer, and Breast Cancer in Young Women. The **World Oncology Forum** (WOF) in collaboration with the *Lancet*, where leading clinicians, researchers, epidemiologists, advocates, policy makers and industry representatives came together “to evaluate progress in the war against cancer” has also become a milestone in ESO calendar. ESO does not just focus its efforts on oncology doctors but it also recognizes the key role that others play in the treatment and care of patients. This makes ESO a true example of a **multidisciplinary organisation**. With this in mind, the School has included nursing in its courses and was an active player in the creation of many European patient advocacy groups. ESO recognizes the importance the media plays in highlighting cancer issues through its annual awards, grants and training courses for journalists. It also provides **media training** for clinicians and other cancer professionals, to help them interact more effectively with the media.

Much of ESO’s work and values are highlighted in its bimonthly magazine **Cancer World**. Cancer World explores the complexity of cancer care from various viewpoints and brings together the social, political, economic and organisational factors that impact on patient experience and outcomes.

**ESO Scientific Committee**

- **Founder**: Umberto Veronesi, Milan
- **Chairman**: Franco Cavalli, Bellinzona
- **Scientific Director**: Alberto Costa, Milan
- **Dep. Scientific Director**: Fedro Peccatori, Milan
- **ESO member**: Felipe A. Calvo, Madrid
- **ESO member**: Alexander M.M. Eggermont, Paris
- **ESO member**: Stan Kaye, Sutton
- **ESO member**: Larry Norton, New York
- **ESO member**: Nicholas Pavlidis, Ioannina
- **ESO member**: Piergiuseppe Pelicci, Milan
- **ESO member**: Bob Pinedo, Amsterdam
- **ESO member**: Lena Sharp, Stockholm (EONS)
- **ESO member**: Stephan Stilgenbauer, Ulm
About the EAU Section of Urological Imaging (ESUI)

The ESUI, a section of the European Association of Urology, aims to increase the knowledge and integrate the know-how on imaging techniques among urologists. With its emphasis on multidisciplinary strategies and goal to improve collaboration with related specialities and affiliates, including radiologists and nuclear medicine physicians, the ESUI offers various activities to its members and other urological professionals.

To complement the EAU’s scientific and educational initiatives, the ESUI organises courses and training during its meetings and participates in the EAU’s broader educational strategies. Over the years, the ESUI’s membership has steadily expanded and its long-term strategies include knowledge-sharing with organisations and specialists groups not only within the urological community but also with other medical disciplines.

Activities
The ESUI organises meetings to present urological imaging at different podia in Europe on a regular basis. One of the main platforms is its annual meeting held in various European cities. These meetings address controversial issues in urology, particularly new developments and challenges in urological imaging, its role in optimal diagnostic and treatment modalities, and the exchange of know-how among the international experts.

Further on, the ESUI is organizing and endorsing clinical trials that evaluate urological imaging in clinical settings. They also organise surveys that address current issues and controversies on a European level. Finally the ESUI is also active in the EAU guidelines process by providing expertise in urological imaging.

ESUI Board
ESUI Chairman Dr. J. Walz, Marseille (FR)
ESUI Board Dr. Brendan Carey, Leeds (GB)
ESUI Board Ass. Prof. Manuel Xavier Ferreira Coelho, Lisbon (PT)
ESUI Board Prof. Petrisor Aurelian Geavlete, Bucharest (RO)
ESUI Board Prof. Tillmann Loch, Flensburg (DE)
ESUI Board Prof. Carlo Trombetta, Trieste (IT)
ESUI Board Prof. Dr. Hessel Wijkstra, Amsterdam (NL)
Ex YAU Officio Dr. J. Futterer, Nijmegen (NL)
The Young Academic Urologists (YAU)

The Young Academic Urologists (YAU) is a group of talented and renowned European young urologists (<40 years old), established few years ago by the EAU as a branch of the Young Urologists Office (YUO).

Members are rigorously selected according to their scientific, clinical and surgical skills; currently, almost 100 members have joined the YAU, working within one the 9 subgroups according to their field of expertise.

**Mission**

YAU’s aims are: to promote high-quality studies in order to provide strong evidence for the best urological practice; to promote educational programmes in order to boost European training standards; to create a platform for close international cooperation for the future urology leaders in Europe.

**Activities**

In the last few years several high quality publications have been promoted, developed and issued by the YAU members as a result of the close and effective relationship between the scientists and centres involved.

Strategic partnerships have been developed with other EAU bodies like the Guidelines Office, the Sections Office and the European School of Urology; as a result, several projects have been successfully finalised in support or in collaboration with the relevant partners.

**YAU board**

F. Sanguedolce (Chair & Working group Endourology & Urolithiasis)
S. D. Brookman-May (Working group Renal Cell Carcinoma)
N. Buffi (Working group Robotic in Urology)
J-N. Cornu (Working group Functional Urology)
C. De Nunzio (Working group BPH)
G. Giannarini (Working group Prostate Cancer)
M. S. Silay (Working group Paediatric Urology)
P. Verze (Working group Men’s Health)
E. N. Xylinas (Working group Urothelial)
Interactive keypads

During the EMUC meeting you are kindly requested to make use of the IML Connectors, the keypads can be used during voting sessions, furthermore you can send text messages to the chair and you can use the keypad as microphone. Please find below the instructions.

How to use the microphone:

When prompted, you can use your Connector to be heard by the audience.

Available Talk now Busy

Press the microphone button on your Connector to turn your microphone on and off.

How to send us your questions and comments...

When prompted, use your keypad to write and send a text message (like writing an SMS on a mobile phone).

There is no predictive texting (T9).

When you have finished press the green button to send.

How to vote using the Connectors...

When the vote is opened, you have 10 seconds to press the button which corresponds with your answer.

Your vote is registered immediately and you will see "Valid" displayed on the screen along with your response.

If you change your mind, simply re-enter a number before the countdown ends.
Astellas has made a commitment to change tomorrow – a commitment that we are bringing to the field of oncology. We aim to create innovative treatments that will genuinely improve the lives of cancer patients. To do this we are focusing our R&D and partnership efforts into precision medicine that will create first-in-class or best-in-class programmes. This has resulted in no fewer than 12 separate therapies under clinical development into conditions including prostate cancer, other solid tumours like breast cancer, lung cancer and bladder cancer, as well as haematological malignancies.

These are the challenges we have set ourselves because Changing tomorrow is more than just words – it is what we must do to give cancer patients real hope of a tomorrow worth looking forward to.

www.astellas.eu
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Sponsor Acknowledgement

The organisers respectfully acknowledge the following sponsors for providing unrestricted educational grants and services to the:
- 7th European Multidisciplinary Meeting on Urological Cancers (EMUC);
- ESU courses on Medical treatment of metastatic renal cancer and Castrate resistant prostate cancer (ESU);
- European School of Oncology: Personalised approach to prostate cancer management (ESO);
- 4th Meeting of the EAU Section of Urological Imaging (ESUI);
- Young Academic Urologists meeting (YAU).

Silver Sponsors

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Industry-Sponsored Symposia

Thursday, 12 November

Room: H1

12.00-13.00  Imaging solution in urology care
MR-guided biopsies and MRI in focal therapy
S. Jenniskens, Nijmegen (NL)

Syngo DynaCT in Urology
M. Ritter, Mannheim (DE)

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Friday, 13 November

Room: Auditorium

12.55-13.55  Exploring patient factors to guide treatment decisions in mCRPC

12.55-13.05  The importance of tailoring treatment decisions in an evolving landscape
A. Alcaraz, Barcelona (ES)

13.05-13.20  “Now that my disease has become more serious, what do we do?”
M. Rouprêt, Paris (FR)
Panelists: S. Osanto, Leiden (NL) and M. De Santis, Coventry (GB)

13.20-13.35  “I’ve always had other health issues. I don’t want my prostate cancer to add to this burden”
M. De Santis, Coventry (GB)
Panelists: M. Rouprêt, Paris (FR) and S. Osanto, Leiden (NL)

13.35-13.50  “People depend on me. I want to fight my disease and get my life back!”
S. Osanto, Leiden (NL)
Panelists: M. De Santis, Coventry (GB) and M. Rouprêt, Paris (FR)

13.50-13.55  Summary and close
A. Alcaraz, Barcelona (ES)

SPONSORED BY ASTELLAS

Room: Auditorium

17.30-18.30  Partnership and participation: forming strong alliances to improve outcomes in mCRPC

17.30-17.35  Welcome and introduction
J. Carles, Barcelona (ES)

17.35-17.50  Partnering in mCRPC to address unmet patient needs
W. Oyen, Amsterdam (NL)

17.50-18.05  Practical strategies to improve patient outcomes with radium Ra 223 dichloride
A. Bjartell, Malmö (SE)

18.05-18.25  Peer-to-peer collaboration in the MDT: an interactive tumour board discussion
J. Carles, Barcelona (ES)

18.25-18.30  Questions from the floor and meeting close
J. Carles, Barcelona (ES)

SPONSORED BY BAYER HEALTHCARE
Saturday, 14 November

Room: Auditorium

13.15-14.15  New paradigms in the management of prostate cancer

13.15-13.20  Welcome and introduction
C. Sternberg, Rome (IT)

13.20-13.35  Individualizing treatment choices based on the biology of the disease
C. Sternberg, Rome (IT)

13.35-13.50  Redefining the management of advanced prostate cancer to optimize survival
N. James, Birmingham (GB)

13.50-14.05  New hopes in high-risk localized prostate cancer
N. Mottet, Saint-Étienne (FR)

14.05-14.15  Summary and implications for the future
N. Mottet, Saint-Étienne (FR)

SPONSORED BY SANOFI ONCOLOGY

Room: H2

18.15-19.15  Managing advanced prostate cancer: Perspectives on the patient's journey

18.15-18.25  Welcome and introduction
C. Hood, London (GB)

18.25-18.45  Beginning the journey: Newly-diagnosed hormone-sensitive metastatic disease: Interactive doctor/patient discussion
H. Payne, London (GB)
C. Webber, London (GB)

How the data supports the management plan: The evolving role of chemotherapy and novel agents in advanced prostate cancer
C. Llorente, Madrid (ES)

Panel Discussion
H. Payne, London (GB)
C. Llorente, Madrid (ES)
N. Tunariu, London (GB)

18.45-19.10  The journey continues: Metastatic castration-resistant prostate cancer: Interactive doctor/patient discussion
H. Payne, London (GB)
C. Webber, London (GB)

How the data supports the management plan: Selecting the right treatment at the right time, what, when, how?
C. Llorente, Madrid (ES)

Panel Discussion
H. Payne, London (GB)
C. Llorente, Madrid (ES)
N. Tunariu, London (GB)

19.10-19.15  Summary and close
C. Hood, London (GB)

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Exhibitors’ Profiles

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The European Association of Urology is a non-profit organisation which supports medical professionals working in the field of urology through many of its scientific, professional, educational and awareness-building initiatives. The overarching mission is to raise the level of urological care in Europe, and for many years this has been done through educational and scientific programmes aimed at urologists. Today the EAU represents more than 14,000 medical professionals working in Europe and beyond its borders. To learn more about the EAU and its membership, visit www.uroweb.org.
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Bullet points:
• A future where no man suffers with or dies from prostate cancer
• To work for all prostate cancer patients in Europe, under one umbrella, for better treatment, care and quality of life
• To support national organisations to deliver services effectively, efficiently and in line with national priorities

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KOELIS is a French MedTech company with 20 employees founded by Antoine Leroy and Patrick Henri, based in Grenoble and now in Boston. KOELIS designs, manufactures and sales surgical navigation devices. Focused on the international market of Urology, our challenge is to bring technological breakthrough and new standards in the personalized diagnosis and treatment of prostate cancer. As an expert in 3D organ mapping, KOELIS ensures quality control and accuracy in surgical interventions. To date, more than 50,000 patients have benefited from KOELIS Technology.

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Abstracts

4th Meeting of the EAU Section of Urological Imaging (ESUI)

Oral Presentations
Thursday, 12 November  14.30–15.15 hrs

Unmoderated Poster Presentations – Poster viewing times
Thursday, 12 November  10.20–10.50 hrs
11.50–13.00 hrs
15.15–15.45 hrs

7th European Multidisciplinary meeting on Urological Cancers (EMUC)

Oral Presentations
Saturday, 14 November  08.50–09.30 hrs

Unmoderated Poster Presentations – Poster viewing times
Friday, 13 November  10.50–11.10 hrs
12.40–13.55 hrs
15.25–16.00 hrs
Saturday, 14 November  11.40–12.00 hrs
13.00–14.25 hrs
16.20–16.50 hrs
Sunday, 15 November  General poster viewing during the programme

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EMUC Oral Presentations

Bladder cancer

**O1 First-line randomized phase 2 study of gemcitabine/cisplatin plus apatorsen or placebo in patients with advanced bladder cancer: The international Borealis-1™ trial**


**Introduction & Objectives:** Heat shock protein 27 (Hsp27) is over-expressed in bladder cancer (BC) and postulated to increase tumour growth, metastasis, and chemotherapy resistance. Apatorsen (A; OGX-427), a novel antisense oligonucleotide, inhibits Hsp27 production and can potentially enhance the efficacy of chemotherapy. This trial was designed to evaluate efficacy and safety of A in combination with gemcitabine and cisplatin (GC) in patients with advanced BC.

**Material & Methods:** Chemotherapy-naïve patients with advanced BC were randomized to GC + A 600 mg, GC + A 1000 mg, or GC + placebo. Patients were stratified by Karnofsky performance status (KPS) and visceral disease. The primary endpoint was overall survival (OS). Prognostic subgroups were retrospectively evaluated using multiple variable modelling and hierarchical step down. A post hoc analysis was performed to explore the hypothesis that Hsp27 inhibition might be relevant to OS in poor prognosis disease.

**Results:** A total of 179 patients were randomized/treated. Median OS was 15.2 months (mo). When compared to GC + placebo, GC + A 600 demonstrated improved OS and PFS (OS HR=0.856 and PFS HR=0.830) versus GC + A 1000 (OS HR=0.858; PFS HR=0.927). Results from the post hoc model revealed that KPS, liver metastasis, alkaline phosphatase, and hemoglobin were prognostic. A median prognostic score dichotomized patients into poor and good prognosis groups (50% each group). Patients with poor prognosis treated with GC+A 600 had a greater reduction in risk of death (HR=0.717) than patients with good prognosis (HR=1.44). The most significant prognostic factor was KPS ≤80% (35% pts in GC + A 600 vs GC) resulting in HR=0.50 in favour of GC + A 600. Overall treatment was well tolerated. Most common Grade ≥3 adverse events (AEs) were neutropenia, anemia, thrombocytopenia and hypertension. Frequency of ≥3 Grade toxicities were: 89% (GC), 93% (GC + A 600) and 95% (GC + A 1000). GC + A 1000 had a higher treatment discontinuation rate due to AEs.

**Conclusions:** Advanced BC patients with poor prognosis benefited from apatorsen 600 mg combined with first line GC. Apatorsen may be impacting the intrinsic biology of patients with poor risk factors. Further evaluation is warranted in this patient population.

Localized Prostate Cancer

**O2 Phase 2 study of investigational oral GnRH antagonist TAK-385 (relugolix) in patients with intermediate risk localized prostate cancer requiring neoadjuvant and adjuvant androgen deprivation therapy (ADT) with external beam radiation therapy (EBRT): Results from the 12-week interim analysis**


**Introduction & Objectives:** TAK-385 is an investigational, oral, non-peptide GnRH-selective antagonist of the human GnRH receptor (IC₅₀ 0.12 nM). This phase 2, randomized, open label, parallel group study (NCT02135445) was designed to evaluate the testosterone (T)-lowering efficacy as well as safety and PK
of TAK-385 (N=60) vs the injectable peptide GnRH antagonist, degarelix (DGX; N=40). We now report results from the prespecified interim analysis conducted after 30 patients had received at least 12 weeks of TAK-385.

**Material & Methods:** Men aged ≥18 years with intermediate risk localized prostate cancer appropriate for EBRT and 6 months ADT, with baseline T >150ng/dL, and PSA >2ng/mL were randomized to receive open label oral TAK-385 320 mg as loading dose on day 1 then 120 mg once daily (QD) or DGX 240 mg on day 1 then 80 mg subcutaneously every 4 weeks (Q4W), for 24 weeks. Patients had at least 12 weeks of ADT prior to EBRT. The primary endpoint was the proportion of patients achieving and maintaining castrate T levels <50ng/dL from the start of week 5 to end of week 24 (5–24 weeks). Secondary endpoints included prostate size reduction, safety, plasma PK, LH levels, and PSA kinetics. PK, T, and/or PSA were assessed on days 1, 2, 4, 8, 15 and 29, and then every 4 weeks, and prostate volume by TRUS/CT/MRI at 8–12 weeks.

**Results:** At data cut-off, 30 patients had received TAK-385 120mg QD (median age 71 yrs [range 60–80]) and 20 patients received DGX 80 mg Q4W (median age 70.5 yrs [58–81]); overall median treatment duration was 19.5 weeks (0.1–25). At 1 day after first dose, median T levels were 50.0 ng/dL (25.1–306.9) with TAK-385 and 49.0 ng/dL (25.1–223.9) with DGX. At 12 weeks, median T was further reduced to 8.2 ng/dL (2.9–53.0) with TAK-385 and 9.7 ng/dL (4.6–27.1) with DGX. T <50 ng/dL was sustained in 93% (TAK-385) vs 85% (DGX) of patients from 5–24 weeks. After 4 weeks, PSA was reduced by a median 70.5% to 2.4 ng/mL (0.3–11.7) with TAK-385 vs 76.4% to 2.0 ng/mL (0.6–14.9) with DGX. At 12 weeks, PSA was reduced by a median 91.6% to 0.6 ng/mL (0.1–5.5) with TAK-385 vs 90.5% to 0.8 ng/mL (0.1–12.7) with DGX. After 8 weeks, median prostate volume reduction was 30% (TAK-385) vs 29% (DGX). TAK-385 PK profile in patients was similar to that in healthy men (MacLean et al, ENDO 2013, Abstract SAT-318); observed 12-week steady state plasma trough concentrations were on average 2-fold higher than the target of 4 ng/mL for sustained castration. At data cut-off, no patients had discontinued due to adverse events (AEs); the most common AEs were (TAK-385/DGX): hot flush (60%/70%), fatigue (7%/15%), and dysuria (0%/15%).

**Conclusions:** Based on these interim results, oral TAK-385 (120mg/day) demonstrated similar rapid T-lowering efficacy vs injectable DGX. PSA response and prostate volume reductions were similar across the 2 arms. The safety and tolerability profile of TAK-385 was acceptable and consistent with the anticipated treatment effect.

**O3 Clinico-dosimetric factors predicting long-term severe urinary incontinence after post-prostatectomy RT: Results of a longitudinal observational study**

B. Noris Chiorda1, C. Sini2, C. Fiorino2, F. Badenchini3, A. Briganti4, A. Chiara1, C.L. Deantoni1, N. Suardi5, A. Briganti4, A. Chiara1, C.L. Deantoni1, N. Suardi5, N. Di Muzio1, F. Montorsi4, N. Di Muzio1, C. Cozzarini1.

**Introduction & Objectives:** The fear of RT-induced urinary incontinence (URINC) often contraindicates post-prostatectomy RT (POPPRT), despite the lack of accurate data about its real incidence and severity. Purpose of this analysis was to analyse clinico-dosimetric factors predicting severe, self-reported, URINC 1 and 2 after POPRT.

**Material & Methods:** In 2012 a longitudinal, observational study aimed at assessing URINC from POPRT including WPRT was activated. For the evaluation of urinary toxicity, 2 validated questionnaires, IPSS and ICIQ-SF, have to be filled-in by pts at baseline, at RT mid-point and end, and at 3 and 6 months after RT end, and every 6 months thereafter. This analysis pertains to the first 101 pts correctly filling the questionnaires at baseline and at 12 months (60 also at 2 years). 54 and 47 pts were treated with ADV and SALV intent after a median of 4 and 38 months, respectively, from RP, with either conventional (n=42) or moderately hypofractionated (n=59) regimens, at a median 2-Gy equivalent dose (EQD2) to the prostatic bed of 70 and 74 Gy in ADV and SALV cohort, respectively, and a median EQD2 dose of WPRT of 50 Gy.

**Results:** The baseline mean ICIQ score was 7.8 and 4.8 in ADV and SALV cohorts, respectively (p=0.009). The corresponding values at 1 and 2 years were 7.4 vs 7.3 and 8.5 vs 7.9, respectively. Severe URINC (≥13 points) was recorded in 23 and 19%, at 1 year, and in 37 and 21%, at 2 years, of pts treated with ADV and SALV intent, respectively (p always ≤0.20). The 75th quartiles of ICIQ at 12 (ICIQ12) and 24 (ICIQ24) months (12 and 13 points, respectively), were set as end-points for regression logistic analysis. Of note, the “most informative cut-off” of baseline ICIQ with respect to the risk of ICIQ12 was ≥16 (AUC 86%) and ≥7 (AUC 87%) in ADV and SALV cohorts, respectively.

**Figure 1.**

Several clinico-dosimetric factors, including age, diabetes, hypertension, pT and pN stage, # of removed LN, RT finality, time from RP to RT, fractionation, EQD2, adjuvant androgen deprivation (AAD), IQIQ and IPSS baseline values, were analysed. Variables with a p-value <0.20 at univariable analysis were entered into a backward stepwise multivariable model indicating baseline ICIQ and nicturia (IPSS item #7) and AAD as predictors of ICIQ12 (AUC 94%), while baseline ICIQ and EQD2 predicted ICIQ24 (AUC 89%).

**Conclusions:** The risk of long-term severe URINC one and two years after POPRT was slightly higher in pts treated with ADV...
The estimated absolute lifetime prostate cancer mortality could potentially benefit from screening before the age of 55 (Table 1). Men diagnosed before the age of 55 were excluded from this study although the estimated proportion at the time of the study (1993–1999) was negligibly small.

Conclusions: The majority (80–90%) of men the that die of prostate cancer would not benefit from starting screening before the age of 55. It could be questioned if the small potential benefit of starting screening before the age of 55 would weigh against advancing the harms of screening for all men by 5–10 years.

Advanced Prostate Cancer

05 Effect of baseline characteristics on overall survival in metastatic Castration-Resistant Prostate Cancer (mCRPC) patients treated with radium-223 in an international early access program (EAP)

Introduction & Objectives: The ALSYMPCA study reported improved overall survival (OS) in symptomatic mCRPC patients (pts) treated with radium-223 (Ra-223) vs placebo (median 14.9 vs 11.3 months [mos], hazard ratio = 0.70). Here we present OS data according to baseline characteristics in pts treated with Ra-223 in an international EAP conducted in 14 countries (Europe, Canada and Israel).

Material & Methods: The EAP was a prospective phase IIIb study of mCRPC pts with symptomatic or asymptomatic bone metastases with no visceral disease (lymph node only metastases were allowed). Pts were to receive Ra-223, 50 kBq/kg (iv injection) every 4 weeks for 6 cycles. Post hoc analyses assessed the effects of baseline characteristics on OS, including Eastern Cooperative Oncology Group performance status (ECOG PS), alkaline phosphatase (ALP) levels (< upper limit of normal [ULN, 120U/L] vs ≥ULN), hemoglobin levels (≥10 g/dL vs <10 g/dL) and pain (mean pain severity score) measured from the brief pain inventory short form (BPI-SF).

Results: 696 pts were treated; of these, 609 (88%) had an ECOG PS of ≤1 and 139 (20%) reported no pain at baseline. Median ALP and hemoglobin levels were 149 U/L and 12.2 g/dL respectively. At the time of analysis, median OS was 16 months (95% CI 13–not available (NA)). OS was significantly different depending on pts ECOG status, ALP levels, hemoglobin levels and reported pain at baseline (Table).
**Table 1:**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
<th>Median OS, mos (95%CI)</th>
<th>Log-rank p-value</th>
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<tr>
<td>All pts</td>
<td>696</td>
<td>16 (13–NA)</td>
<td></td>
</tr>
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<td>ALP* &lt;ULN</td>
<td>272</td>
<td>NA (16–NA)</td>
<td>&lt;0.0001</td>
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<tr>
<td>ALP* ≥ULN</td>
<td>422</td>
<td>12 (11–15)</td>
<td></td>
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<td>Hemoglobin &lt;10g/dL</td>
<td>56</td>
<td>7 (5–9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Hemoglobin ≥10g/dL</td>
<td>640</td>
<td>17 (14–NA)</td>
<td></td>
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<td>ECOG PS 0</td>
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<td>NA (17–NA)</td>
<td>&lt;0.0001</td>
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<td>ECOG PS ≥2</td>
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<tr>
<td>Pain No</td>
<td>139</td>
<td>NA (16–NA)</td>
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</tr>
<tr>
<td>Pain Mild</td>
<td>370</td>
<td>14 (13–NA)</td>
<td></td>
</tr>
<tr>
<td>Pain Moderate/severe</td>
<td>158</td>
<td>11 (9–13)</td>
<td></td>
</tr>
</tbody>
</table>

Pts with missing data *n=2, †n=29.

**Conclusions:** OS was longer in pts with lower ALP levels, hemoglobin levels higher than 10 g/dL, good ECOG PS, and in those who reported no pain at baseline. Further studies are required to investigate whether pts at an earlier stage of their disease with similar prognostic factors benefit more from Ra-223 compared with those at a later stage.

**O6 SWOG 0421: Impact of circulating markers of bone metabolism on overall survival in men with metastatic Castration Resistant Prostate Cancer (CRPC)**

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**Introduction & Objectives:** Skeletal metastasis is observed in the majority of men with advanced prostate cancer and is a frequent source of morbidity. In these patients, the homeostatic balance between bone formation and resorption is frequently disrupted, with predominance of osteoblastic activity manifesting as sclerotic bony disease. This disruption is clinically assessable with circulating serum markers of bone metabolism.

We previously reported in men with bone-metastatic CRPC as part of SWOG 0421, a phase III trial of docetaxel +/- atrasentan, that these blood-based biomarkers have significant independent prognostic value and that a small group of CRPC patients with highly elevated markers preferentially benefit from bone-targeted therapy (Lara, et al. JNCI 2014). Here, we report our analysis of the contribution of these markers individually or collectively as prognostic factors for overall survival (OS) adjusted for known clinical covariates in the S0421 dataset.

**Material & Methods:** Markers for bone resorption (N-telopeptide [NTx] and pyridinoline [PYD]) and formation (C-terminal collagen propeptide [CICP] and bone alkaline phosphatase [BAP]) were measured in pre-treatment sera collected from men in the SWOG 0421 trial. Log-transformed levels of the markers and clinical covariates (including age, baseline PSA, performance status, and pain score, among others) were individually assessed for association with OS by univariate Cox regression. Significant risk factors were included in a multivariate Cox regression model for OS; bone markers were added individually and collectively to this model in a stepwise selection process. Receiver operating characteristic (ROC) curves were constructed for risk factor models +/- bone markers. The contribution of bone markers to prognostic risk groupings was also assessed.

**Results:** 750 patients with evaluable bone marker and clinical data were included. Median age was 69 years with median PSA of 77 ng/dL; 417 (56%) had performance status ≥2; 304 (41%) had pain score ≥4; and 457 (61%) were on bisphosphonate therapy. Each of bone markers significantly contributed to the final Cox model, with higher levels associated with worse OS. A Cox stepwise selection model adjusted for clinical covariates showed that the best combination was with BAP (Hazard Ratio [HR]=1.15, p=0.008), CICP (HR=1.27, p=0.0007), and PYD (HR=1.21, p=0.047). In ROC analysis, the AUC of clinical covariates for OS prognostication was 0.73; this significantly improved with the addition of CICP (AUC = 0.76, p = 0.003) or BAP (AUC 0.75, p = 0.004) or combination BAP/CICP/PYD (AUC = 0.76, p = 0.001). Prognostic groups based on risk of death at 2 years (low: <35% probability; medium: 35–70%; high >70%) were identified. 82 men were upstaged to a higher risk group while 98 were down-staged when bone markers were added to the model.

**Conclusions:** Baseline circulating markers of bone metabolism are independently associated with worse OS in bone-metastatic CRPC. ROC analysis showed that bone markers add to clinical covariates in significantly improving prognostic accuracy. Prognostic subgroups of CRPC patients with differential OS outcomes were identified, with risk reclassification seen in a substantial proportion when bone markers were considered. These results have critical implications for CRPC clinical trial design and bedside patient prognostication.
EMUC Unmoderated Poster Presentations

Localized Prostate Cancer

P001
Natural history of prostate widespread HGPIN and ASAP: When to rebiopsy?


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Introduction & Objectives: Widespread HGPIN (high-grade prostatic intraepithelial neoplasia, wHGPIN) and ASAP (atypical small acinar proliferation) are frequent findings on prostate biopsy, known for their precancerous potential. The likelihood of finding prostate cancer (PCa) on rebiopsy is estimated up to 55% for wHGPIN and 34–60% for ASAP, warranting an early rebiopsy. The natural history of these lesions, however, is not thoroughly known, nor the timing of rebiopsy. Aim of our study was to evaluate the natural history and the long-term PCa risk of wHGPIN and ASAP in a large multicentric series of who underwent a subsequent re-biopsy, establishing the real need and effective timing for rebiopsy.

Material & Methods: We retrospectively evaluated data of 1012 patients who underwent prostate biopsy between 2001 and 2010, negative for PCa but positive for HGPIN, wHGPIN and/or ASAP. We included in study 802 patients (79.3%) who received at least one re-biopsy during follow-up; all these patients were followed-up with periodical urological visits comprehensive of PSA measurement and digital rectal examination (DRE). All specimens underwent central pathological review.

Results: Of 802 patients, 62% of patients remained cancer-free at a mean follow-up of 6 years. The cumulative risk of PCa was 25% for monofocal HGPIN, 28% for wHGPIN, 36% for ASAP and 43% in case of simultaneous ASAP+HGPIN. 50% of PCa diagnoses occurred within 12 months, 80% within 3 years. In more than 90% of cases, PCa identified on re-biopsy was low-grade (Gleason ≤7). Age, PSA levels and number of biopsies at baseline were not significant cancer predictors in patients with precancerous lesions. PCa diagnosis-free survival at 24-months follow-up was 80.5% for monofocal HGPIN, 78.9% for wHGPIN, 74.1% for ASAP and 68.9% for ASAP+HGPIN. No significant differences were found among groups in the first 12-months follow-up (Figure 1).

Conclusions: Findings of ASAP and ASAP+HGPIN are strong risk factors for a subsequent PCa diagnosis; on the other hand, the risk of developing PCa in wHGPIN seems not so different from monofocal HGPIN, and thus general population. A rebiopsy is advised in ASAP+HGPIN patients, possibly after 12 months of follow-up. The choice for an earlier rebiopsy or a rebiopsy after HGPIN alone should be guided by clinical factors such as PSA and DRE.

P002
-2Pro PSA and prostate health index usefulness for the diagnostic of prostate cancer with PSA range between 3 and 10 ng/mL


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Introduction & Objectives: The high incidence of prostate cancer (PCa) in worldwide and the growing interest in overdiagnosis and overtreatment have made the study of new markers imperative for helping us predict the presence and aggressiveness of the tumor.

Material & Methods: A prospective study including 101 patients with PSA levels between 3 and 10 ng/mL and normal digital rectal exam was conducted between November 2013 and November 2014. All patients underwent prostate biopsy and level determination of PSA, free PSA and -2proPSA. The -2pro PSA ratio (%2proPSA) and Prostate Health Index (PHI) were also calculated from this data.

Results: A total of 101 patients were included in a one-year period evaluation time. Patients had a mean age of 63.7 years old. The means of PSA and free PSA ratio (%fPSA) were 6.06 ng/mL and 16%, respectively. The means of -2proPSA and %2proPSA were 16.8% and 1.8%, respectively. The prostate volume mean was 46 cc and the PSA density mean was 0.19 ng/cc. In the univariate analysis, only %fPSA and PHI showed statistical significant association with the presence of tumor in prostate biopsy, whereas %2proPSA almost reached statistical significance.

In the multivariate analysis, PHI showed the best area under the curve (AUC) with a value of 0.749, followed by %fPSA (0.708) and -2proPSA (0.671). The best values for internal and external validity of each of the evaluated parameters turned out to be for PHI, with 93%
sensibility and 37% specificity, 53% positive predictive value (PPV) and 88% negative predictive value (NPV). **Conclusions:** PHI is the parameter that allows predicting the presence of PCa more precisely for patients with normal digital rectal exam and PSA between 3 and 10 ng/mL.

**P003**

**Validation of a new urine test for the early diagnosis of clinically significant prostate cancer**

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**Introduction & Objectives:** To reduce the over diagnosis and over-treatment of insignificant tumours there is an urgent need for a specific test to detect clinically significant prostate cancer (PCa). Using gene expression profiling specific PCa-biomarkers were identified. Eight promising biomarkers were selected and the diagnostic accuracy was tested in urine of an intent-to-treat cohort. The aim of this study was to clinically validate the four-gene biomarker panel (HOXC6, DLX1, TDRD1 and HOXC4) using an independent prospective multicenter study cohort.

**Material & Methods:** In two independent prospective, multicenter studies (cohort 1: n = 492 and cohort 2: n = 371) urine was collected after digital rectal examination (DRE) from men undergoing prostate biopsies based on an elevated serum PSA level (≥3.0 ng/mL) and/or suspicious DRE. KLK3, HOXC4, HOXC6, TDRD1 and DLX1 mRNA levels were measured using RT-qPCR. The assay was validated according to MIQE criteria, hence the test is a standardized Laboratory Developed Test (LDT). Results from cohort 1 were used to develop models with (combinations of) the four genes based on the comparative CT method. The chosen model was validated in cohort 2, i.e. a fully independent validation cohort.

**Results:** PCa was identified in 41% (202/490) and 47% (174/371) of men from the studies respectively. The model with the combination of HOXC6/DLX1 resulted in the highest average AUC (0.76) and specificity (36%) at ~90% sensitivity, based on cohort 1. Furthermore, HOXC6 and DLX1 were significant in the logistic regression, in 96% and 94% respectively. This model was independently validated for the diagnosis of PCa with Gleason score ≥7 in prostate biopsies. Using ROC curve analysis HOXC6/DLX1 outperformed PCA3 in both cohorts (cohort 1 AUC = 0.75 vs. 0.64; cohort 2 AUC = 0.73 vs. 0.62). Adding serum PSA to the HOXC6/DLX1 model resulted in an AUC of 0.81 and 0.80, respectively.

**Conclusions:** This study showed the promising results of a new urine test for the early diagnosis of clinically significant PCa using a model which combines HOXC6 with DLX1. These results demonstrate that this model could be used to assess the risk of PCa with Gleason score ≥7 and therefore could reduce the amount of unnecessary prostate biopsies.

**P005**

**Usefulness and predictive value of PSA density, Adjusted by transition zone volume, in North-African men with PSA levels between 2 and 4 ng/ml**

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**Introduction & Objectives:** The cut-off level of prostate-specific antigen (PSA) at 4.0 ng/mL has been the most important and widely used value in the screening, detection and monitoring of prostate cancer. The aim of this study is to assess the diagnostic significance of prostate-specific antigen (PSA), density (PSAD) and PSA density adjusted by transition zone volume (PSATZD) in men with PSA levels between 2.0 and 4.0 ng/mL.

**Material & Methods:** Between 2000 and 2010, 138 men with PSA levels between 2.0 and 4.0 ng/mL underwent transrectal ultrasonography (TRUS) and 12-core prostate biopsy. Diagnostic accuracies for various cut-offs of PSAD and PSATZD were investigated according to subdivided PSA levels of 2.0 to 3.0 ng/mL and 3.1 to 4.0 ng/mL.

**Results:** The detection rate of prostate cancer was 23, 8% (3/134). The percentage of patients with extracapsular disease was 28.1% (10/32) and primary Gleason grade 4 or 5 was obtained in 8/32 cases (25%) patients. The transition zone volume and PSATZD in cancer cases were significantly different in comparison with those in non-cancer cases. The area under the receiver operating characteristic curve for PSATZD was significantly higher in comparison with that for PSAD in the same subdivided PSA ranges. The diagnostic efficiency for PSATZD was higher than that for PSAD. The diagnostic efficiency showed the highest value at the cut-off level for PSATZD of 0.23 and 0.28 in men with PSA levels of 2.0 to 3.0 ng/mL and 3.1 to 4.0 ng/mL, respectively.

**Conclusions:** The use of PSATZD cut-offs as a biopsy indication may reduce many unnecessary biopsies without missing most prostate cancer cases in the PSA range of 2.0 to 4.0 ng/mL.

**P006**

**The 4Kscore test predicts upgrading at prostatectomy among men with low-grade prostate cancer on prostate biopsy**

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**Introduction & Objectives:** While many of these men are candidates for active surveillance, a proportion may have a bad outcome owing to aggressive prostate cancer that was missed on initial biopsy. A recent prospective study confirmed the 4Kscore Test accurately predicts the risk of aggressive cancer on prostate biopsy. The purpose of this study was to analyse if the 4Kscore could predict the presence of Gleason ≥7 in a cohort of men with low-grade tumours on prostate biopsy who underwent radical prostatectomy.

**Material & Methods:** A recent large, US multi-center prospective trial enrolled 1312 men referred for prostate biopsy for suspicion of prostate cancer regardless of age, PSA, digital rectal exam findings or prior biopsy status. Prior to TRUS-guided prostate biopsy, blood was collected for a 4Kscore test. The 4Kscore calculates the risk of high-grade (Gleason ≥7) prostate cancer on prostate biopsy by a blood test that measures levels of four kallikrein biomarkers (total PSA, free PSA, intact PSA, and human kallikrein-2) plus age, DRE findings, and prior
biopsy status. We used all men who were found to have low-grade (Gleason 6) cancer on biopsy and underwent radical prostatectomy (RP) for this analysis. We assessed the association of the 4Kscore test with the risk of tumour upgrading found in the surgical specimen. Chi squared test was used to evaluate the association.

Results: Among the 1312 men enrolled in this trial, 144 men were found to have prostate cancer and underwent radical prostatectomy. Of these men who elected to undergo surgical extirpation, 50 men had Gleason 6 cancer on prostate biopsy, of which the RP pathology revealed 42% (21) men had Gleason ≤6 prostate cancer, 52% (26) men had Gleason 7 prostate cancer, and 4% (2) men had Gleason ≥8 cancer. One patient was found not to have cancer at surgery. Using a 4Kscore cut off of 7.5%, tumour upgrading occurred in significantly more men with a 4Kscore ≥7.5% vs. men with a 4Kscore <7.5% (67% vs. 35%, p=0.034). For a 4Kscore cut off of 20%, tumour upgrading occurred in 85% (11/13) men with a 4Kscore ≥20%, significantly more than tumour upgrading in men with a 4Kscore <20% (p=0.016).

Conclusions: In men who had Gleason 6 disease on biopsy and underwent RP, higher 4Kscores were associated with tumour upgrading at surgery. Men with 4Kscores >20% and Gleason 6 prostate cancer on biopsy have the highest likelihood of harbouring Gleason ≥7 disease and as such these men may not be suitable candidates for active surveillance protocols.

P007
Criteria used by urologists to determine sides of nerve-sparing surgery in radical prostatectomy
H.H.M. Al-Itejawi, J.A. Nieuwenhuijzen, R.J.A. Van Moorselaar, A.N. Vis, VU University Medical Centre, Dept. of Urology, Amsterdam, The Netherlands

Introduction & Objectives: Nerve-sparing radical prostatectomy (NS-RP) is widely performed in patients with localized prostate cancer in an effort to retain erectile function and possibly urinary continence after surgery. It remains unclear in which patients NS-RP is oncologically safe and in which patients NS-RP should be performed for optimal functional outcome. Present Dutch guidelines and the guidelines of the EAU do not give clear recommendations on the criteria to perform NS-RP.

Material & Methods: Through this study, we wanted to evaluate the considerations and clinical criteria that urologists use to select patients for NS-RP.

We conducted an online survey, to determine how urologists performing RP make this assessment. Eighty-nine urologists were invited to fill in the questionnaire on NS-RP. Questions were subdivided in the following categories: general patient characteristics, clinical prognostic parameters, radiological criteria with a specific focus on multiparametric MRI (mpMRI), pathological prognostic criteria. Furthermore, patient-related expectations were accounted for.

Results: The survey was completed by 72 urologists (80.9% of total), of which 68.1% (49 urologists) perform radical prostatectomy (16.3% open, 18.4% laparoscopic, 73.5% RALP as a first surgeon), and almost all 98.0% (48 urologists) perform NS-RP.

See table 1 for an overview of the percentage of urologists who use one of the parameters as decision points for NS-RP.

Table 1. Percentage of urologists that uses one of the parameters as decision points for NS-RP

<table>
<thead>
<tr>
<th>Parameter</th>
<th>% urologists using parameter to determine side of NS-RP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validated sexual function questionnaire pre-operatively (SHIM or IIEF)</td>
<td>55.1%</td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
</tr>
<tr>
<td>cT3</td>
<td>59.2%</td>
</tr>
<tr>
<td>Age</td>
<td>65.3%</td>
</tr>
<tr>
<td>Radiology, mpMRI</td>
<td>28.1%</td>
</tr>
<tr>
<td>Pathological</td>
<td></td>
</tr>
<tr>
<td>Gleason score ≥8</td>
<td>95.9%</td>
</tr>
<tr>
<td>Tumor volume</td>
<td>90.0%</td>
</tr>
<tr>
<td>Shared decision making</td>
<td>93.8%</td>
</tr>
<tr>
<td>Nomograms</td>
<td>59.2%</td>
</tr>
</tbody>
</table>

Conclusions: Clear recommendation to perform NS-RP do not yet exist. In our survey, different poor prognostic clinical, radiological, and pathological prognostic parameters had influence on the decision of the urologists to perform NS-RP. As of yet, the decision to NS-RP remains largely one that is taken by the urologist based on his or her own interpretation of a wide set of clinical, radiological, and pathological prognostic parameters.

P008
Prostate specific antigen isoforms in assessment of tumour extension in prostate cancer patients
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Introduction & Objectives: Prostate specific antigen (PSA) and its free (f-PSA) and total (t-PSA) isoforms are commonly used in clinical practice. Clinical data have demonstrated that Pro-PSA and associated prostate health index (PHI) could increase specificity and sensitivity of PSA assessment in prostate cancer (PC) patients. The aim of the study was to assess efficacy of combined PSA assessment with 3 isoforms in correlation with clinical and morphological characteristics of the disease.

Material & Methods: Serum concentrations of f-PSA, t-PSA and Pro-PSA were assessed with chemiluminescence method (Beckman Coulter Access 2) in 223 PC patients, undergone surgical treatment. Morphological stage pT2a-T2b was verified in 12 patients, pT2c in 138, pT3a in 38 and pT3b in 35. Postoperative Gleason score was 5–6 in 113 (50.6%) patients, 7 (3+4) in 64 (28.7%), 7 (4+3) in 30 (13.4%) and 8–10 in
16 (7.2%) patients. Low risk PC was classified as: morphological stage ≤pT2, Gleason score ≤6; clinically significant PC as: stage ≥pT3 and Gleason score ≥7 (3+4).

**Results:** Mean serum concentrations of t-PSA (12.5±0.9 vs 10.3±0.6, p=0.039), f-PSA (9.0±0.6 vs 10.5±0.4, p=0.029) and PHI (79.2±4.6 vs 64.8±2.9, p=0.009) significantly differed in subgroups of PC patients with Gleason grade 7 (3+4) and 5–6, respectively. Moreover, significant difference was observed in serum concentrations of Pro-PSA (33.0±4.0 vs 21.3±1.5, p=0.008), %Pro-PSA (3.2±0.3 vs 2.4±0.1, p=0.013) and PHI (114.6±12.1 vs 79.2±4.6, p=0.008) in subgroups of PC patients with Gleason score 7 (3+4) and 7 (4+3), respectively. In subgroups with ptT2a-b and ptT2c difference in concentrations of PSA isoforms was not significant. In subgroups with pT3b and pT3c disease difference in concentration of t-PSA (14.6±0.1 vs 114.6±0.1, p=0.013) and PHI (119.1±10.0 vs 91.8±7.1, p=0.030) was statistically significant. In subgroups with ptT3b and ptT3a disease significant differences were observed only for concentrations of Pro-PSA (35.5±3.6 vs 25.8±2.6, p=0.032), %Pro-PSA (3.2±0.2 vs 2.6±0.1, p=0.019) and PHI (119.1±10.0 vs 91.8±7.1, p=0.030).

**Conclusions:** Complex assessment with 5 PSA isoforms (t-PSA, f-PSA, Pro-PSA, %Pro-PSA and PHI) could increase accuracy of preoperative PC staging.

**P009**

**Individualized HIFU treatment for prostate cancer. Long term results of one of the pioneer centre**

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**Introduction & Objectives:** Being one of the pioneer centres of HIFU, we analyzed our data since 2000 of PCA patients treated with Ablatherm®.

**Material & Methods:** Over 1100 consecutive patients were analyzed with up to 14 years of follow-up. They were grouped per risk category and treatment regimen. 715 patients have a full follow-up of at least 5 years, 98 of more than 10 years. M+ and systemic therapy free survival rates are analysed.

**Results:** No need for systemic therapy in the Low and Intermediate risk groups at 5 and 10 years after primary HIFU, only 11% needed a salvage local treatment for full tumor control (local rec.). Most went for salvage HIFU treatment, but all local salvage treatments remain possible after HIFU. Systemic therapy was needed in the High risk, T3a group and salvage therapy grp in only 4% of patients within 5 years after primary HIFU and in 22% of T3a patients with at least 10 years of follow-up. In the High risk and T3a group >95% of patients reached full tumor control after primary HIFU treatment, only 16% needed salvage local treatment (most salvage HIFU) at 5 years after primary HIFU. Only 3.5% needed systemic treatment.

**Conclusions:** In case of local recurrence after primary HIFU, HIFU can be safely repeated and ALL salvage treatment options and choices for the patient remain possible.

**P010**

**A prospective randomized study to compare functional outcomes of radiofrequency and ultracision scapelss in videolaparoscopic radical prostatectomy**

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**Introduction & Objectives:** To compare the recovery of continence and erectile function after laparoscopic extraperitoneal radical prostatectomy using two different surgical devices, namely, Ultracision and Ligasure, for dissection and hemostasis.

**Material & Methods:** One hundred thirty two males with localized prostate cancer were prospectively enrolled for the study and subjected to laparoscopic extraperitoneal radical prostatectomy. They were randomly divided into two groups: Group A comprising of 66 patients and Group B comprising of 66 patients. Surgery of Group A patients was conducted using radiofrequency scalpel whereas, the surgery of Group B patients was conducted using ultrasonic scalpel. The recovery of urinary continence and erectile function of the patients were assessed by self-administered questionnaires (International Continence Society Questionnaire and International Index of Erectile Dysfunction) at 15 days before surgery, and 90 and 180 days after prostatectomy.

**Results:** Differences in operative time, intra- and perioperative complications, and postoperative hospital stay for the two groups were statistically insignificant. Patients treated with radiofrequency (LigaSure) showed better recovery of continence and erectile functions compared to patients treated with ultrasonic scalpel (Harmonic) at 180 days after surgery, as shown by a statistically significant difference between ICIQ-UI (p=0.0016) and IIEF 5 (p=0.0352) scores.

**Conclusions:** In this study, radiofrequency provided better functional outcomes compared to ultrasonic scalpel in patients subjected to extraperitoneal LRP. This may be attributed to the low lateral spreading of the device, which allowed to limit the damage of tissues not directly involved in the dissection and hemostasis.
P011
Are early continence recovery and oncological outcomes influenced by use of different devices in prostatic apex dissection during laparoscopic radical prostatectomy?


Introduction & Objectives: Treatment of prostate cancer has evolved considerably in the last decade, especially in terms of minimisation of the negative impacts on erectile function and continence to ensure good quality of life for treated patients. New surgical devices, such as dissectors and haemostatic scalpels, allow precise definition of the surgical field with finer dissection of the anatomic structures, with subsequent reductions in operative times and better oncological and functional outcomes. Although monopolar scissors (MS) are still widely used, radiofrequency (RF) and ultrasound (US) scalpels have been recently introduced in laparoscopic radical prostatectomy (LRP). However, despite the widespread use of these scalpels, few studies have compared these devices in terms of oncological and functional outcomes after radical prostatectomy. The present study aimed to prospectively assess the impact of MS, RF and US scalpels on margin status at apex and recovery of urinary continence and erectile function in patients undergoing extraperitoneal LRP.

Material & Methods: A total of 150 men were prospectively enrolled between September 2009 and April 2013 and postoperatively evaluated for continence and clinical factors.

Results: There were no differences in terms of operative times (p = 0.94), blood loss (p = 0.96), apical margin positivity (p = 0.39) or postoperative hospital stay (p = 0.94) between the groups. Moreover, no differences in the functional outcome scores, as evaluated by the International Consultation on Incontinence self-administered Questionnaire, at 1, 3, and 6 months post-surgery were observed.

Conclusions: Our study represents the first evaluation of continence recovery in LRP with respect to different devices used for prostatic apex dissection. We found that the oncological, functional, and operative outcomes were similar between these different devices during LRP, with no scalpel demonstrating superiority in continence recovery.

P012
Transparency of pathologic results after radical prostatectomy in the Benelux


Introduction & Objectives: The oncological outcome after radical prostatectomy (RP) is negatively influenced by a positive surgical margin (PSM), as it increases the risk of tumour recurrence. The likelihood of PSM is strongly influenced by the preoperative tumour stage (TNM, PSA and Gleason score) and by the surgeon's experience, irrespective of the RP technique. Analysis of the incidence of PSM contributes to improvement of ones surgical technique. Still, in case of PSM, salvage radiotherapy might offer curative solutions. Only a few centres in the Benelux have published data on PSM. To stimulate more transparency in this topic, we present our serie.

Material & Methods: 355 EERPE (endoscopic extraperitoneal RP)-patients from a single-surgeon database were gathered prospectively in the period of 2006–2014 and analyzed retrospectively. A chi-square test was performed to calculate the significance of different hypotheses. A literature study was performed to compare with other urologic departments in the Benelux.

Results: Patient characteristics are listed in Table 1. 73.8% of the patients belonged to the intermediate or high risk category according to d'Amico. 63.4% of our patients received a LPLND during the EERPE. Of all EERPE's 36.6% resulted in a PSM, 23.9% of the pT2 and 62.4% of the pT3 tumors. Tumour progression was found to be a significant risk factor for PSM. Table 3 shows a comparison of with those available in the Benelux. The NVU-database contains 4142 of 19200 Dutch RP's from 2006–2014.

Conclusions: Our series shows acceptable oncologic outcome concerning PSM after RP in our population. Current data on PSM in the Benelux are poor, incomplete and insufficient for critical evaluation of oncological outcome of RP.

Table 1. Patient characteristics in our series

<table>
<thead>
<tr>
<th>Mean (range) n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative</td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>64 (44–76)</td>
</tr>
<tr>
<td>Gleason score</td>
<td>6.5 (4–10)</td>
</tr>
<tr>
<td>PSA (ug/L)</td>
<td>19.1 (0.87–190)</td>
</tr>
<tr>
<td>d'Amico risk</td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>93 (26.2)</td>
</tr>
<tr>
<td>High</td>
<td>113 (31.8)</td>
</tr>
<tr>
<td>cT-stadium</td>
<td>149 (42.0)</td>
</tr>
<tr>
<td>cT1a-c</td>
<td>151 (42.5)</td>
</tr>
<tr>
<td>cT2a</td>
<td>38 (10.7)</td>
</tr>
<tr>
<td>cT2b</td>
<td>42 (11.8)</td>
</tr>
<tr>
<td>cT2c</td>
<td>112 (31.5)</td>
</tr>
<tr>
<td>cT3</td>
<td>12 (3.4)</td>
</tr>
<tr>
<td>rT3</td>
<td>12 (3.4)</td>
</tr>
<tr>
<td>Perioperative</td>
<td></td>
</tr>
<tr>
<td>Nerve sparing procedure</td>
<td>Unilateral</td>
</tr>
<tr>
<td>Bilateral</td>
<td>68 (19.2)</td>
</tr>
<tr>
<td>Total</td>
<td>150 (42.3)</td>
</tr>
<tr>
<td>LPNND</td>
<td>225 (61.4)</td>
</tr>
<tr>
<td>Estimated blood loss (cc)</td>
<td>530 (10–6600)</td>
</tr>
<tr>
<td>Overall OR time (min)</td>
<td>210 (103–430)</td>
</tr>
<tr>
<td>Postoperative</td>
<td></td>
</tr>
<tr>
<td>Pathological tumor stage</td>
<td>pT2</td>
</tr>
<tr>
<td></td>
<td>pT3</td>
</tr>
<tr>
<td></td>
<td>Total</td>
</tr>
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</table>

Table 2. Results Chi-square test of PSM in our series

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>RR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Nerve sparing procedure</td>
<td>0.85</td>
<td>0.64–1.13</td>
<td>0.272</td>
</tr>
<tr>
<td>(2) Bilateral-unilateral</td>
<td>1.24</td>
<td>0.78–1.98</td>
<td>0.355</td>
</tr>
<tr>
<td>(3) Pathological tumor stage (pT2–pT3)</td>
<td>2.60</td>
<td>2.00–3.40</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 3. Summary of publications on PSM in RP in the Benelux

<table>
<thead>
<tr>
<th>Reference</th>
<th>Origin</th>
<th>Type</th>
<th>N</th>
<th>PSM rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roumeguere et al. 2003 [7]</td>
<td>Belgium</td>
<td>RRP</td>
<td>77</td>
<td>73</td>
</tr>
<tr>
<td>Mottrie et al. 2007 [2]</td>
<td>Belgium</td>
<td>RALP</td>
<td>184</td>
<td>16</td>
</tr>
<tr>
<td>Roumeguere et al. 2003 [7]</td>
<td>Belgium</td>
<td>RRP</td>
<td>77</td>
<td>73</td>
</tr>
<tr>
<td>Mottrie et al. 2007 [2]</td>
<td>Belgium</td>
<td>RALP</td>
<td>184</td>
<td>16</td>
</tr>
<tr>
<td>Roumeguere et al. 2003 [7]</td>
<td>Belgium</td>
<td>RRP</td>
<td>77</td>
<td>73</td>
</tr>
<tr>
<td>Mottrie et al. 2007 [2]</td>
<td>Belgium</td>
<td>RALP</td>
<td>184</td>
<td>16</td>
</tr>
</tbody>
</table>

*Incomplete database with selection bias.

Conclusions: Our series shows acceptable oncologic outcome concerning PSM after RP in our population. Current data on PSM in the Benelux are poor, incomplete and insufficient for critical evaluation of oncological outcome of RP.
P013
Intra-surgical total and re-constructible pathological prostate examination for safer margins and nerve preservation: Istanbul preserve
Y. Saglican1, U. Ince1, O.B. Argun1, C. Obek2, T. Ilter3, M. Panagiota3, M.B. Tuna4, S. Keskin5, A.R. Kural6, 1Acibadem University, Dept. of Pathology, Istanbul, Turkey; 2Acibadem University, Dept. of Urology, Istanbul, Turkey; 3Cerrahpasa School of Medicine, Dept. of Urology, Istanbul, Turkey; 4Aile Hospital, Dept. of Urology, Istanbul, Turkey

Introduction & Objectives: Performing frozen section (FS) analysis during radical prostatectomy improves nerve-sparing without compromising cancer control. Techniques described focus on FS of tissue adjacent to the neurovascular bundle (NB) and result in significant tissue loss not allowing for perfect reconstruction for final whole-mount evaluation. We describe a novel FS technique in which the entire prostate is examined for margins and perfect reconstruction is conceivable.

Material & Methods: 54 patients underwent intra-surgical total and re-constructible pathological prostate examination for safer margins and nerve preservation (Istanbul preserve) during nerve-sparing robot-assisted radical prostatectomy between 10/2014 and 6/2015. Prostate was removed via extending the lateral 12-mm. assistant port and incision re-tightened with suturing. Hemostasis, lymphadenectomy (LND) and anastomosis were performed during FS. A genitourinary pathologist and 2 technicians were involved. Prostate tissue adjacent to NVB was inked with 3 different colors depicting apex, mid and base. The right and left lobes were also inked separately. Prostate was cut from each half border, hematoxylin and eosiin stained, and reviewed. If margin was positive (R1) extensively, further resection was performed from the corresponding NB area until negative margins were reached. If R1 was a small focus, excised tissue from corresponding area was sent for permanent analysis. In large prostate, anterior zone was not always examined.

Results: The risk categories were low, medium and high in 8, 31, and 16 patients, respectively. LND was performed in 52 (96%). Median time for pathologic analysis was 55 (35–95); overall operative time was 34 mins longer in cases with FS and LND. Twenty-four patients (44%) had R1 at surgery and further tissue was resected; 25%, 41% and 60% with increasing risk category. Malignant tissue was found in 8% of resected bundle tissue. Two patients had R1 at permanent pathology. False negative rate of R1 at FS was zero. All prostates were reconstructed with negligible tissue loss for final whole mount examination.

Conclusions: Preserve allows for intra-surgical complete pathological examination of the prostate for margin status and for perfect re-construction for whole mount permanent examination. It guarantees safer margins together with increased rate of nerve sparing.

P014
External radiation-therapy versus brachytherapy in low risk prostate cancer. RECAP-database analysis
J.R. Pastor Peidro1, J. López Torrecilla1, J. Jove Teixido2, C. González San Segundo1, A. Cabeza Rodríguez3, E. Villafranca Iturbe4, E. Collado Ballesteros5, A. Gómez Caamaño6, V. Muñoz-Garzón7, C. Vallejo Ocaña1, 1Hospital General Universitario De Valencia, Dept. of Radiotherapy Oncology, Valencia, Spain; 2Hospital Germans Trias i Pujol, Dept. of Radiotherapy Oncology, Badalona, Spain; 3Hospital Gregorio Marañón, Dept. of Radiotherapy Oncology, Madrid, Spain; 4Hospital Doce De Octubre, Dept. of Radiotherapy Oncology, Madrid, Spain; 5Hospital De Navarra, Dept. of Radiotherapy Oncology, Pamplona, Spain; 6Hospital La Fe, Dept. of Radiotherapy Oncology, Valencia, Spain; 7Hospital De Santiago, Dept. of Radiotherapy Oncology, Santiago De Compostela, Spain; 8Hospital Do Meixoeiro, Dept. of Radiotherapy Oncology, Vigo, Spain; 9Hospital Ramón y Cajal, Dept. of Radiotherapy Oncology, Madrid, Spain

Introduction & Objectives: The guidelines consider external radiation therapy (ERT) and brachytherapy (BT) valid options in radical treatment of low risk prostate cancer patients. We analyse and compare overall survival (OS), biochemical relapse free survival (BRRS), metastases free survival (DMFS), cancer specific survival (CSS) and toxicity in two treatment options.

Material & Methods: Multicenter retrospective comparative study of 1,341 low risk prostate cancer patients treated 986 with ERT and 355 with brachytherapy (31 HDR and 324 LDR). We used data from the RECAP database (November 1994-December 2013) and described clinical control and toxicity (RTOG/EORTC and CTCAE scoring) results. Descriptive statistics, survival estimates determined by Kaplan–Meier and comparisons of survival rates were performed using Log-rank test.

Results: The median follow up was 58.9 months (73.2m in ERT-group and 42.4m in BT-group). The median of ERT doses was 74Gy (56–80Gy) and median CTVprostate-D100 in BT-group 130.3Gy (9.5–151.7Gy). The 5-years results was: OS 92.7% vs 99%, BRFS 90.3% vs 89.2%, DMFS 98.8% vs 99.4% and CSS 99.3% vs 100% in ERT group and BT-group respectively. Toxicity was described in Table 1. There were statistically differences in genito-urinary, haematuria and rectal bleeding worst in ERT. In BT-group there was 2 dead by haematuria. No grade 5 toxicity in ERT-group.

Table 1. Toxicity ≥ grade 2

<table>
<thead>
<tr>
<th>Genito-urinary</th>
<th>Gastro-intestinal</th>
<th>Haematuria</th>
<th>Rectal bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERT 14.3%</td>
<td>2.6%</td>
<td>3.1%</td>
<td>4.6%</td>
</tr>
<tr>
<td>BT 4.2%</td>
<td>0%</td>
<td>0.8%</td>
<td>2%</td>
</tr>
<tr>
<td>P&lt;0.001</td>
<td>P=ns</td>
<td>P&lt;0.001</td>
<td>P=0.016</td>
</tr>
</tbody>
</table>

Conclusions: ERT and BT are very effective in the treatment for low risk group patients without differences in cancer control. The toxicity seems slightly worst in ERT group. But the follow up and number of patients is so different between two treatments.

P015
Role of [11C]choline PET/CT as an image method for target delineation in patients with oligometastatic prostate cancer
G. Beltramo1, A. Bergantin2, F. Ria1, A.S. Martinotti1, L. Redaeli1, M. Invernizzi1, A. Vai1, L.C. Bianchi1, L. Bossi Zenetti1, P. Gandolfo2, 1Centro Diagnostico Italiano, Dept. of Cyberknife, Milan, Italy; 2Centro Diagnostico Italiano, Nuclear Medicine Unit, Milan, Italy

Introduction & Objectives: [11C]choline PET/CT has been established as a diagnostic tool in re-staging patients with biochemical failure after radical treatment for prostate cancer...
in particular for its capability to detect the presence of lymph node and bone metastases.

The knowledge of the anatomical site of recurrence may be useful to refer patients to the specific tailored therapy, in addition to the conventional anti-hormonal therapy.

We investigated the role of $^{[11]C}$choline PET/CT as an image method for target volume definition and delineation in patients with oligometastatic prostate cancer for Cyberknife stereotactic tailored therapy.

**Material & Methods:** Between March 2009 and March 2013 a cohort of 30 patients with up to 3 synchronous lymph node prostate oligometastases staged with $[11]$C$^{[1]}$choline PET/CT (47 lesions, median volume 12.92 cc, range 0.39–111.67), following biochemical recurrence after local curative treatment were treated with Cyberknife Stereotactic Body Radiotherapy (SBRT) in our Center. In all patients $[11]$C$^{[1]}$choline PET/CT images was used to select and to delineate target volumes at lymph node recurrent sites. The mean age of patients population at the time of the Cyberknife treatment was 68 years (range 55–84). Cyberknife prescription doses were 3000–3600 cGy delivered in 3 consecutive fractions of 1000–1200 cGy. In 14 lesions (37%) SBRT was performed as re-irradiation (the recurrent lesion was situated in the previously irradiated volume).

**Results:** The Cyberknife treatment was well tolerated without any acute or late toxicity at all. There were no in field recurrence, resulting in a local control of 100%. Eleven and 3 patients, respectively required a second and third salvage treatment for metachronous metastatic disease. The median time to clinical progression was 14 months (range 3–54). After a median follow up of 33 months (range 13–73) 16 patients started with Androgen Deprivation Therapy (ADT) because of polymetastatic disease resulting in an ADT-FS of 80% at 1 year and 65% at 2 years. The median time ADT was deferred resulted of 26 months (range 4–56).

**Conclusions:** The recent evidence of the potential toxic nature of ADT suggest that effective local therapy might reduce the burden of systemic therapies usually given to patients with metastatic prostate cancer. Although there are not literature data that support the use of $[11]$C$^{[1]}$choline PET/CT to plan target volume at lymph nodal level our preliminary results are promising, showing that the treatment is well tolerated with excellent rate of local control and suggest a potential role of $[11]$C$^{[1]}$choline PET/CT to select and refer patients to specific treatment strategies.
Multicentric study of permanent brachytherapy in younger patients with prostate cancer

E. Villafranca Iturrei, P. Fernandez, R. Martinez-Monge, C. Gutierrez, A. Sola, E. Collado Ballesteros, I. Herruzo, De Navarra, Dept. of Radiation Oncology, Pamplona, Spain; 1Complejo Hospitalario De Navarra, Dept. of Radiation Oncology, Pamplona, Spain; 2Instituto Oncologikoa, Dept. of Radiation Oncology, San Sebastian, Spain; 3Clinica Universidad De Navarra, Dept. of Radiation Oncology, Pamplona, Spain; 4Hospital Carlos Haya, Dept. of Radiation Oncology, Malaga, Spain; 5Hospital Ramon y Cajal, Dept. of Radiation Oncology, Madrid, Spain; 6Hospital Meixoeiro, Dept. of Radiation Oncology, Vigo, Spain; 7Hospital Infantia Cristina, Dept. of Radiation Oncology, Badajoz, Spain

Introduction & Objectives: To evaluate biochemical progression-free survival (BDFS) in men 60 years of age or younger with prostate cancer who underwent exclusive permanent brachytherapy.

Material & Methods: 528 patients with LR/IR: T1: 423p, T2: 105p; Gleason 6: 520p. 8p: neoadjuvant hormone therapy: 48p; initial PSA ≤10: 492p, <10ng/ml in 83 (39.1%) cases. Biopsy Gleason sum <7 was registered in 94 (44.3%), >7 in 118 (55.7%) patients. Postoperatively the tumours were categorized as pT3a in 105 (49.6%), pT3b in 84 (39.6%), pT4 in 21 (10.8%) specimens. Lymph node involvement occurred in 77 (36.3%) cases. The American Society for Radiation Oncology (ASTRO) guidelines were used. A Cox regression model was used to determine the independent factors associated with biochemical failure.

Results: No factor had influence in the analysis of prognostic factors of BDFS. However BDFS 10y pD90 <145Gy: 86% vs. D90 >165Gy: 87.8% vs. D90 >165Gy: 92.5% (HR: 1.47, p: 0.46).

Conclusions: This is one of the biggest series at the moment in younger men with permanent brachytherapy. There is a trend to get better results with D90 >165Gy. Multicentric study of permanent brachytherapy in younger patients with prostate cancer

Does adjuvant therapy improve results of radical prostatectomy in patients with locally-advanced prostate cancer and positive surgical margins?

V.A. Chernyava, B. Alekseev, E.I. Veliev, M.I. Volkova, D.I. Volodin, N.V. Vorobiev, A.D. Kaprin, V.V. Kapustin, A.A. Krasheninnikov, O.B. Loran, V.B. Matveev, K.M. Njushko, E.A. Sokolov, K.M. Figurin, V.I. Shirokorad, N.N. Blokhin Cancer Research Center, Dept. of Urology, Moscow, Russia; Pherzen Moscow Oncology Research Institute, Dept. of Urology, Moscow, Russia; Russian Academy of Postgraduate Education, Dept. of Urology, Moscow, Russia; Moscow City Oncology Hospital No. 62, Dept. of Urology, Moscow, Russia; Moscow City Oncology Hospital No. 62, Dept. of Diagnostic Ultrasound, Moscow, Russia

Introduction & Objectives: To assess an impact of adjuvant therapy (AT) on oncological outcomes after radical prostatectomy in patients with locally-advanced prostate cancer and positive surgical margins (SM+).

Material & Methods: We performed a retrospective multicenter analysis of medical records of 212 patients with locally-advanced prostate cancer and SM+ after radical prostatectomy performed between 1997 and 2012. Median age of the patients was 62.0 (41–78) years. Initial PSA was <10ng/ml in 50 (23.6%), 10–20ng/ml in 79 (37.3%), >20ng/ml in 83 (39.1%) cases. Biopsy Gleason sum <7 was registered in 94 (44.3%), >7 in 118 (55.7%) patients. Postoperatively the tumours were categorized as pT3a in 105 (49.6%), pT3b in 84 (39.6%), pT4 in 21 (10.8%) specimens. Lymph node involvement occurred in 77 (36.3%) cases. The American Society for Radiation Oncology (ASTRO) guidelines were used. A Cox regression model was used to determine the independent factors associated with biochemical failure.

Results: No factor had influence in the analysis of prognostic factors of BDFS. However BDFS 10y pD90 <145Gy: 86% vs. D90 >165Gy: 87.8% vs. D90 >165Gy: 92.5% (HR: 1.47, p: 0.46).

Conclusions: This is one of the biggest series at the moment in younger men with permanent brachytherapy. There is a trend to get better results with D90 >165Gy. Does adjuvant therapy improve results of radical prostatectomy in patients with locally-advanced prostate cancer and positive surgical margins?
P023
Long term Toxicity and quality of life after high-dose-rate brachytherapy as monotherapy for low- and intermediate-risk prostate cancer

S. Aluwini1, W. Busser1, J. Boormans2, W. Kirkels2, J. Praag1, P. Jansen1, I-K. Kolkman-Deurloo1, C. Bangma2. 'Erasmus MC – Daniel den Hoed, Dept. of Radiation Oncology, Rotterdam, The Netherlands; 2Erasmus MC – Daniel den Hoed, Dept. of Urology, Rotterdam, The Netherlands

Introduction & Objectives: The use of HDR brachytherapy (HDR-BT) as monotherapy for prostate cancer (PC) is increasing worldwide with good tumour control rates and acceptable toxicity. To date limited data have been published from prospective studies regarding this regimen. Here we report our results on quality of life (QoL), toxicity and clinical outcomes after HDR-BT monotherapy for PC patients.

Material & Methods: In prospective QoL registration study, 166 patients with histologically confirmed PC clinical stage T1b-T2b, Nx-0, Mx-0, Gleason score (GS) ≤7, PSA ≤15ng/ml and WHO performance status of 0–2 were treated with HDR-BT monotherapy. Were treated with HDR-. Intervention: Patients underwent one implant HDR-BT as monotherapy to a total dose of 38 Gy in four fractions.

Genitourinary (GU) and gastrointestinal (GI) toxicities were prospectively assessed using EORTC-RTOG questionnaires and physicians charts. QoL was evaluated using EORTC QLQ-PR25 and IPSS questionnaires. Biochemical Failure (BF) was determined according to the Phoenix definition.

Results: Three months after treatment, acute GU and GI toxicities were reported in 10.8% and 7.2%. Acute toxicity resolved within two months in the majority of patients (61%). Late grade ≥2 GU and GI toxicity were reported in 19.7% and 3.3% of patients 12 months after HDR-BT. Mean QLQ-PR25 scores showed clinically relevant changes from baseline for urinary symptoms and sexual functioning with no clinically relevant changes for bowel symptoms. With a mean follow-up of 35 months, biochemical failure was observed in 2.4%. Overall survival at 60 months was 93.6% and cancer-specific survival was 100%.

Conclusions: HDR-BT monotherapy for localized PC showed excellent clinical outcome and acceptable acute and late toxicity. Urinary symptoms and sexual function QoL decreased after treatment.

P024
Prognostic role of neutrophil-to-lymphocyte ratio and platelet-to-lymphocyte ratio in patients treated with radical prostatectomy


Introduction & Objectives: Evidence has shown that inflammatory response plays an important role in the development of various cancers. This inflammatory pathway has been related with some urological cancers (renal, prostate, bladder). Neutrophil-to-lymphocytes ratio (NLR) and platelets-to-lymphocytes ratio (PLR) may be indicators of this response. In the present study we evaluate the prognostic significance of NLR and PLR in patients with prostate cancer treated with radical prostatectomy in our centre.

Material & Methods: We retrospectively analysed 208 patients with histologically confirmed prostate cancer who underwent radical prostatectomy from January 2008 to February 2014. Patient pre-operative hemogram parameters of neutrophil count, lymphocyte count and platelet count were assessed. NLR and PLR were calculated from this data. We classified these patients in two groups; those who presented a prostate specific antigen level >0.2 ng/mL in two consecutive tests were considered as biochemical recurrence (BR) group. The other group didn’t present this characteristic (noBR). The differences between groups for the variables total neutrophils, total lymphocytes, total platelets, PLR and NLR were calculated by T-Student/U-Mann Whitney test depending on whether the variables distribution was normal or not. We also compared these two groups creating propensity score-matched cohorts, based on pre-treatment D’Amico’s risk score and follow-up.

Results: 208 patients were evaluated, mean age 62 years, mean follow-up 37.8 months. 177 patients were classified in no-BR group and 29 patients in BR group (mean time to biochemical recurrence 20.44 months). We calculated the differences between these two groups for the variables total neutrophils (p=0.108), total lymphocytes (p=0.551), total platelets (p=0.804), PLR (p=0.626) and NLR (p=0.529) without finding statistically significant differences. Even after matching both groups no differences were observed in any of the studied variables.

Conclusions: Although the studied parameters have been suggested to be effective and economical predictors of recurrence in prostate cancer, this fact could not be confirmed in our analysis. Further investigation is necessary to elucidate the role of NLR and PLR as prognostic indicators in prostate cancer.

P025
Prospective evaluation on the outcome of inclusion of a multiparametric MMRI scan in MRI naïve patients with low risk prostate cancer, already established on active surveillance

T. Suntharasivam, R. Uppor, O.N. Eronini. North Cumbria University Teaching hospital, Dept. of Urology, Carlisle, United Kingdom

Introduction & Objectives: Active surveillance (AS) is well established as an option in patients with low risk disease. Protocols are aimed at minimising under staging the disease and identifying progression. Recent NICE guidelines in the UK have incorporated the routine use of MRI at the initial evaluation of new cases. The role of MRI in previously naïve patients with otherwise stable parameters is uncertain and requires evaluation. This prospective study describes the outcome on management of a delayed MRI on a cohort of patients already established on active surveillance.

Material & Methods: A prospective review of the outcome of Multiparametric MRI (MMRI) using a 1.5 Tesla MRI in a single centre over 3 months (March 2014 to May 2014). The Inclusion criteria were all MRI Naive men established and stable on AS due for a review. All patients underwent a MMRI which was reviewed by a uro radiologist and the outcome following a case review with the results from the MMRI incorporated in the treatment algorithm were recorded and analysed. We report the outcome on the results from the MMRI on patient management intention.

Results: 30 patients on AS (range 6–36 months) met the criteria for inclusion in the analysis (Stable PSA and organconfined on DRE). On review 6 were excluded. MMRI on remaining 24 patients was undertaken and the impact on management analysed. Based on MMRI, 12(50%) patients were advised to continue with active surveillance without further biopsy. 5(21%) patients were advised to proceed with treatment options in view disease progression on MMRI. 7(29%) patients underwent surveillance biopsy due to equivocal finding in MRI.

Conclusions: Delayed MMRI has a role in improving the risk stratification of patients who appear stable on AS. Its inclusion in
the follow-up algorithm of these patients, resulted in a change of management, or intervention in 50% of patients evaluated. MMRI potentially selected out 21% of the study group as being high risk and requiring active treatment. The results suggest that even in this small group of patients that the late inclusion of MRI can help select out unsuitable cases despite otherwise stable parameters.

**P026**
The prophylactic irradiation of the pelvic LN after prostatectomy does not increase the risk of secondary malignancies: A single Institution analysis of 1109 patients with 10 years follow-up

C. Sini1, C. Cozzarini2, C. Fiorino1, C.L. Deantoni2, B. Noris Chiorda2, A. Fodor4, A. Chiarà2, L. Perna1, R. Calandrino1, N. Di Muzio2, 1San Raffaele Scientific Institute, Dept. of Medical Physics, Milan, Italy; 2San Raffaele Scientific Institute, Dept. of Radiation Oncology, Milan, Italy

**Introduction & Objectives:** To evaluate a possible role for prophylactic irradiation of the pelvic lymph-nodal area (WPRT) in the postoperative setting for prostate cancer (PCa) in increasing the risk of potentially radiation-induced second malignancies (SM).

**Material & Methods:** From 1993 to 2011, 1109 patients (pts) (median age 65 years) were treated with postoperative ADV (n = 739) or SALV (n = 370) non conformal RT (n = 169), 3DCRT (n = 670) or static-fields IMRT (SS-IMRT, n = 57) at 1.80 Gy/fr (median dose 70.2 Gy), with moderately hypofractionated regimens (median dose 2.35 Gy/fr) with Tomotherapy (n = 213) at a median 2 Gy equivalent (EQD2, v/alpha=3) dose of 70 Gy. WPRT was delivered to 336 pts at a median EQD2 dose of 50 Gy. 510 pts received adjuvant hormonal therapy for a median of 21 months. The median follow-up (FU) was 124 months.

**Results:** 139 pts developed SM, including 73 in-field (IN) and 66 out-field (OUT), after a median of 65, 80 and 56 months, respectively. At univariate analysis, there was no statistical difference of 10-year risk SM/IN/OUT for pts receiving prostatic bed (PB) only or PB+WPRT (Figure 1a). No role emerged for RT dose, technique or fractionation. A borderline predictive role of the 10-year risk of SM was found in patients experiencing any (acute/late) GU+GE Grade ≥2 (p = 0.12), while GE and GU G ≥2 showed a correlation with the risk of IN (p = 0.21) and OUT (p = 0.12), respectively. Age showed a statistically significant correlation with the risk of SM (p ≤ 0.05). Of note, only for patients treated with WPRT, a slight correlation between IMRT techniques and increased risk of OUT (p = 0.26, HR=1.78) emerged (Figure 1b). Multivariable analysis, including all variables with p65 years in all subgroups.

**Conclusions:** Though preliminary, this study does not indicate any additive risk of SM arising from the use of prophylactic WPRT in the postoperative setting for PCa. Overall, the risk of SM development appeared fundamentally as a function of aging. Nevertheless, in the sole pts treated with WPRT a slight correlation, absolutely to be confirmed, between IMRT techniques and risk of OUT emerged. An analysis focused on tumours arose at least 5 years after RT has been precluded owing the low number of events (n = 47, 4%).

**P027**
Prospective evaluation of urinary function in patients with prostate cancer treated with external beam radiation therapy

F. Badenchini1, C. Cozzarini2, B. Avuzzi3, A. Fodor2, T. Rancati4, C. Sini1, R. Valdagni2, N. Di Muzio2, C. Fiorino1. 1Prostate Program, Fondazione IRCCS Istituto Nazionale Dei Tumori; 2San Raffaele Scientific Institute, Dept of Radiation Oncology, Milan, Italy; 3Fondazione IRCCS Istituto Nazionale Dei Tumori, Dept of Radiation Oncology, Milan, Italy; 4Fondazione IRCCS Istituto Nazionale Dei Tumori, Prostate Program, Milan, Italy; 5San Raffaele Scientific Institute, Dept. of Medical Physics, Milan, Italy; 6Prostate Program, Fondazione IRCCS Istituto Nazionale Dei Tumori, Dept of Radiation Oncology, Milan, Italy

**Introduction & Objectives:** To prospectively evaluate urinary symptoms using the International Prostate Symptom Score (IPSS) in patients with localized prostate cancer (CaP) treated with radical (RTT) or post-prostatectomy (PRT) radiotherapy delivered with conventional (CONV) or moderately hypofractionated (HYPO) fractionation.

**Material & Methods:** We considered patients enrolled in the two multicentric prospective observational studies DUEO1 (RRT, CONV and HYPO) and IHU WPRT TOX (RRT and PRT, including irradiation of the pelvic lymph-nodal area, CONV and HYPO). The IPSS questionnaire (evaluating 7 symptoms) is filled-in before and at the end of RT, then 3 and 6 after treatment end and every 6 months thereafter up to 5 years after the end of treatment. In this preliminary analysis only data relative to first year will be analysed.

**Results:** The analysis pertains to 146 RRT CONV pts, 104 RRT HYPO pts, 74 PRT CONV pts and 94 PRT HYPO. The median age in the 2 studies was 71 (RRT) and 66 (PRT) years (p = 0.0001). Overall, urinary function was always better in the RRT CONV cohort. Statistically significant differences among the 4 groups have emerged with respect to urinary frequency, urgency, effort, nocturia. When comparing RRT vs PRT, frequency (p = 0.007) and stress (p = 0.01) were significantly more present in PRT, while only a borderline difference in terms of urgency (p = 0.07) was evident.
Conclusions: These preliminary results seem to suggest that RRT would result in less deterioration of urinary symptoms over time than PRT. Further analyses are ongoing in order to study the effect of baseline urinary situation, age, doses to the bladder and the impact of urinary symptoms on quality of life. This study is supported by AIRC Investigational Grant IG14603 and IG13090.

P028
Predictors of acute and 1-year hematological toxicity after whole-pelvis post-prostatectomy radiotherapy
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Introduction & Objectives: Hematologic toxicity (HT) is an important side-effect of whole pelvis radiotherapy (WPRT). The aim of this study was to evaluate the incidence, severity and predictors of acute and late HT after prophylactic irradiation of the pelvic lymphnodes for prostate cancer (PCa) in postoperative chemo-naïve patients (pts).

Material & Methods: From October 2012, a prospective observational study designed to evaluate the intestinal, hematological and urinary toxicities from WPRT was activated. 125 pts treated with ADV (n = 73) or SALV (n = 52) intent (static field IMRT: 19; VMAT: 61; Tomotherapy (TT): 45), with conventional (CF, 1.80 Gy/ft, n = 39) or HYPO fractionation (median 2.35 Gy/ft, n = 86) were considered. Dose to the prostate bed ranged: 72–75.6 Gy (CF) and 65.8–72.8 Gy (HYPO); dose to nodes: 50.4 Gy (CF) and 51.8 Gy (HYPO). HT was obtained for a blood count pre-RT, at middle and end of RT, at 3–6–12 months and every 6 months from the end of RT. Clinical and dosimetric data were collected. Contours of pelvic bones, used as a surrogate for pelvic bone marrow (BM), were delineated: Ilium (IL), lumbarosacral spine (LS), lower pelvis (LP) and whole pelvis (WP). HT was scored according to CTCAE and as % variation from baseline for white blood cells (WBC), absolute neutrophil (ANC) and lymphocyte (ALC) counts, red blood cells (RBC), hemoglobin (Hb) and platelets (PLT).

Results: A significant and persisting decline in total WBC and, even more markedly, of ANC, while the reduction of RBC, Hb and PLT was less severe (Fig. 1a). All patients who developed acute lymphopenia G1+, of which 89% and 37% G2+ and G3+ but, surprisingly, without any significant infection. Acute G3 lymphopenia was 31%, 45% and 33%, and late G2 at 1 year from RT end 8%, 23% and 19% for pts that underwent TT, VMAT and IMRT, respectively. At multivariate analyses, two robust predictive models of lymphopenia were developed: ALC at baseline (ALCbase) and WP-V40 (AUC = 0.73) were associated to acute G3 lymphopenia; ALCbase, IL-V40 and smoking (AUC = 0.90) to late G2 lymphopenia (Fig. 1b). Best cut-off values (assessed by ROC) discriminating pts with/without lymphopenia were: ALCbase ≤1830/μL and WP-V40 >599.4 cc (acute); ALCbase ≤1780/μL and IL-V40 >94.6 cc (late).

Conclusions: HT after WPRT can be severe and prolonged, but it might be reduced by the application of specific dose-volume constraints to pelvic BM. Supported by AIRC Investigational Grant #14603
P029
The REQUITE project: Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality of life in cancer survivors
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Introduction & Objectives: To present the REQUITE project “[Validating Predictive Models and Biomarkers of Radiotherapy (RT) toxicity to reduce side-effects and improve quality of life in cancer survivors]” and first results on the enrollment and acute toxicity of prostate cancer (Pca) patients (pts).

Material & Methods: The European Union funded REQUITE project involves centers in Europe and the USA. The objectives of the project are to: Carry out a multicentre, cohort study collecting blood samples, standardized epidemiology and treatment data, longitudinal side-effect and quality of life data (before and after treatment, years 1 and 2); produce a centralized database and biobank of DNA for 5300 patients; validate clinical/dosimetric predictors of RT toxicity and incorporate biomarker data; design interventional trials to reduce long-term side-effects; provide a resource for dissemination and exploitation to the RT community. The project focuses on cancers of the breast, lung and prostate. For PCa the primary endpoint is rectal bleeding at 2 years.

Results: Forms were produced to collect standardized clinical and toxicity data. Patient reported toxicity questionnaires were developed and translated into the languages of the collaborating institutes. The questionnaires were validated to check for reliability, compliance and acceptability and are freely available (www.requite.eu). A centralized database was established for data collection, including storage of complete dosimetric information in DICOM RT format. Enrolment started in April 2014 and will end in August 2016. In the first year 697 Pca pts were enrolled: 10% low risk pts, 26% intermediate and 64% high risk. 60% pts received radical RT (neoadjuvant hormone therapy in 55 pts) and 40% post-prostatectomy; 95% external beam RT (prescription doses: 60–85 Gy, 2 Gy equivalent, alpha/beta = 3 Gy), while 5% pts received brachytherapy. Data on acute toxicity at RT end (as measured by CTCAE 4.03) are available for 365 pts. Distribution of acute gastro-intestinal (GI) and genitourinary (GU) toxicity is presented in the figure.

Conclusions: REQUITE is proving the feasibility of a prospective standardized collection of epidemiological/dosimetric/toxicity data coupled to centralized storing of biological material. Meanwhile a large database is being created, which will be of value also for future research in the field of radioinduced side effects. REQUITE is funded by European Community, grant 601826.

P030
Erectile dysfunction a post-open radical prostatectomy. Prospective analysis of results
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Introduction & Objectives: Erectile Dysfunction (ED) is defined as the persistent inability to achieve and maintain sufficiently hard erection to have satisfactory sexual intercourse. Post-open radical prostatectomy due to prostate cancer describes post-operation sexual potency rates ranging between 10% and 93%. The objective of our study is to determine the erectile function rate in patients subjected to open-radical prostatectomy at our centre before and after surgery, likewise the degree of sexual satisfaction.

Material & Methods: Prospective study on all male patients subjected to an open radical prostatectomy due to prostate cancer at our centre, between 1 January 2013 and 31 October 2013 inclusive. To assess sexual potency, the International Index Erectile Function (IIEF-5) was applied on the day prior to surgery and one year post-surgery. Data were analysed using the statistics program SPSS15.0.

Results: 44 patients were included in the study with a mean age of 62.5±4 years. Over 30% of the men had a cardiovascular risk factor. Over half the sample analysed presented with erectile dysfunction (ED) prior to surgery, which in 34% of the cases as a medium. Those patients without prior erectile dysfunction, 48% suffered medium or moderate and 33% severe erectile dysfunction, 1 year post-surgery. Over 40% of the patients experiencing erectile dysfunction again post-surgery were satisfied with sexual intercourse in over half the occasions. 43% of patients with erectile dysfunction post-
surgery rejected any kind of treatment (PDE-5i/ alprostadil intracavernosal or intrarethral injection).
Surgeon’s experience (>5 years), was correlated with a 6–7% reduction in moderate and severe erectile dysfunction rates.

**Conclusions:** To establish the anatomical and physiological changes which occur after any operation, we need to know the patient’s basal situation. In our case, 52% of the men presented a certain degree of sexual impotence pre-surgery. The surgeon’s experience resulted in a reduction in erectile dysfunction severity. Although limited by the sample size, our results are similar to the mean sexual potency rates described post-open radical prostatectomy (15% of the patients without prior erectile dysfunction). The price of the drugs and fear of side effects limited the acceptance of the erectile dysfunction treatment.

**P031**

**Influence of late toxicity on quality of life in patients with low- and intermediate-risk prostate cancer treated with HDR brachytherapy boost in combination with external-beam radiotherapy**

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**Introduction & Objectives:** High-dose-rate brachytherapy (HDR-BT) is a safe and effective treatment option for prostate cancer (PC) and has been used either as a boost after external beam radiotherapy (EBRT) or as monotherapy. Low toxicity and excellent clinical outcome rates have been reported for HDR-BT. However, prospective validated questionnaires to monitor the long-term toxicity of HDR-BT and data on health-related quality of life (HRQoL) for this treatment option is scarce.

We report our long-term (>10 years FU) results on the influence of late toxicity on HRQoL of HDR-BT boost combined with EBRT.

**Material & Methods:** Between 2000 and 2007 a total of 264 low- and intermediate-risk PC patients were treated with HDR-BT boost (3×6 Gy) combined with EBRT (25×1.8 Gy). All treated patients were hormone-naïve.

Genitourinary (GU) and gastrointestinal (GI) toxicities were prospectively assessed using the EORTC-RTOG questionnaires and physicians’ charts for at least 10 years after treatment. The HRQoL was assessed by the prostate-specific EORTC QLQ-PR25 questionnaire. The PR-25 questionnaires were sent to all patients at fixed time points after the treatment. We compared the HRQoL scores of patients with late GU and GI toxicity of grade ≥2 group (A) versus patients with grade 0–1 late toxicity group (B) by applying the Mann-Whitney test. The HRQoL was compared in the period till the median late toxicity incidence rate (11.5 years) was reached between the two groups for three domains (urinary symptoms, bowel symptoms and sexual function) of the PR-25. For all domains a difference of ≥10 points was considered clinically relevant according to Osoba et al.

**Results:** At a median follow up of 108 months (range 0–165) a total of 84 patients (33%) developed grade ≥2 late GI (28 patients) and GU (61 patients) toxicity.

The urinary symptoms domain showed clinically relevant increase (>10 points) in group A (25 points) versus (13 points) in group B. This increase was statistically significant (p < 0.001).

In the sexual function domain there was a lower function score in group A (50 points) versus (63 points) in group B. Although the difference was statistically not significant (p = 0.073), the decrease of more than 10 points is clinically relevant.

The median bowel symptoms score showed an increase of four points in group A patients compared with group B patients.

Although statistically significant (p < 0.001), the increase of only four points seems clinically not relevant. The overall survival at 5 and 10 years was 93% and 83%, respectively.

**Conclusions:** After a FU of more than 10 years in PC patients treated with a combination of HDR-BT and EBRT, the development of grade ≥2 late toxicity led to a substantial decrease in HRQoL for urinary symptoms and sexual function domains but not for bowel symptoms.

This reflects the importance of improving treatment modalities to limit (late) toxicity as this directly has impact on the patient’s quality of life in the long-term.

**P032**

**Multi-variable models predicting specific acute urinary symptoms: Results of a cohort study**

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**Introduction & Objectives:** To assess clinical/dosimetric factors affecting acute urinary toxicities on a large cohort of patients (pts) treated with radical radiotherapy (RT) for prostate cancer.

**Material & Methods:** The final dataset of a prospective multicentre study (DUE01) was considered. It included 539 pts treated with conventionally (74–80 Gy at 1.8–2 Gy/fr) or moderately hypofractionated RT (65–75.2 Gy at 2.2–2.7 Gy/fr). Before the start of RT several clinical and full planning data were prospectively collected for each pts. Based on previous results, bladder absolute (cm2) weekly dose-surface histograms (DSHw) were chosen as dosimetric descriptors.

Acute urinary symptoms (symp) were evaluated through the International Prostate Symptom Score (IPSS) before and after RT. It takes into account seven items [feeling of incomplete bladder emptying (EMP), frequency (FRQ), intermittency (INT), urgency (URG), weak stream (WST), straining (STR) and nocturia (NOC)], each scored from 0 (absence of the symp) to 5 (symp almost always present), for a total of 35 points.

A multivariate logistic regression (MVR) was performed on all the endpoints. The choice of relevant factors to be included was carried out through an in silico methodology combining a bootstrap resampling, a backward feature selection based on minimization of residuals and a basket analysis of bootstrapped models. A synthetic index, called normalized area (NArea), was defined for ranking each predictor to include in MVR.

**Results:** IPSS scores before and after RT were available for 429 pts.

EMP was reported by 30/393 pts, FRQ by 69/398, INT by 38/403, URG by 54/392, WST by 72/574, STR by 32/414 and NOC by 72/380 pts. The resulting models are shown in Table 1.

The role of pre-treatment urinary symp was confirmed as a risk factor for most endpoints together with medium-high weekly bladder doses. Smoke was a risk factor for EMP, INT and URG.
(OR between 2.36 and 3.30), while peripheral AD is protective for some endpoints with OR around 0.40–0.60, reasonably due to its effect on prostate volume and thus on IPSS scores.

<table>
<thead>
<tr>
<th>Table 1: Results of MVR performed on all the endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> EMP</td>
</tr>
<tr>
<td>DSH at 10 Gy (continuously)</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Stroke</td>
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</table>

**Conclusions:** Multi-variable models of acute urinary toxicity were developed based on the results of a large prospective study: Models show to be well calibrated ($R^2 = 0.82–0.98$) with a moderately high discriminative power (AUC: 0.67–0.77).

**P033**

**Quality of life of men on active surveillance for prostate cancer versus men without prostate cancer: Are there any differences?**

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**Introduction & Objectives:** Patient reported outcomes (PRO) have learned us that men on active surveillance (AS) for prostate cancer (PC) usually reported good levels of well-being and that they did not appear to suffer major negative psychological impact of their disease. Longer follow-up PROs are scarce for men who choose AS as well as a comparison of results to a reference group of men without PC. The objective of this study therefore was to compare PROs of men who have been on AS for 5 years to an age-matched cohort of men without PC. The objective of this study was to compare PROs of men who have been on AS for 5 years to an age-matched cohort of men without PC. The objective of this study therefore was to compare PROs of men who have been on AS for 5 years to an age-matched cohort of men without PC. The objective of this study therefore was to compare PROs of men who have been on AS for 5 years to an age-matched cohort of men without PC.

**Material & Methods:** The Prostate cancer International: Active Surveillance (PRIAS) study is an ongoing prospective, observational cohort study with approximately 5,000 patients included from 17 countries. For this study Dutch PRIAS participants with ≥4 years of follow-up were invited to participate. As a reference group we invited an age-matched cohort of screening arm participants from the Rotterdam section of the European Randomised study of Screening for Prostate Cancer (ERSPC) without PC. Men received a quality of life (QoL) questionnaire which included the SF-12, EQ-VAS, STAI-6 (general anxiety), EPIC (urinary, bowel and sexual function) and the MAX-PC (PC-related anxiety).

**Results:** Response rates for the AS and reference group amount to 72% (120/166) and 75% (204/273). The mean age of men on AS is 72 years vs. 74 years for men in the reference group. The median SF-12 mental component summary (MCS) and physical component summary (PCS) scores amounted to 54.6 and 50.6 (AS); 53.0 and 48.6 (reference). For the MCS domain the observed difference was statistically significant, but not clinically relevant. General anxiety scores (STAI-6) seem comparable (median 30.0 vs. 33.3 for the AS and reference group). Disease-specific anxiety (MAX-PC) for men on AS decreased compared to earlier reported PROs after 18-months of follow-up (PC anxiety 8.0 vs. 7.0; PC progression 4.0 vs. 3.0). With respect to the EPIC urination domain (including amongst others urinary function, urinary bother and urinary incontinence) both groups reported high scores, ranging from 89.9 to 93.6 (scale ranges from 0–100, with higher scores indicating better QoL). For the EPIC sexuality domain, the sexual function and sexual bother scores amounted to 40.9 and 83.3 (AS); 35.2 and 83.3 (reference).

**Conclusions:** Men who follow an AS management strategy for a longer period of time seem to experience good physical and mental health. Because the general anxiety scores in the two groups seem comparable, and the cancer-specific scores decrease slightly compared to PROs reported after 18-months of follow-up, it is suggested that men that choose to stay on AS can handle the thought of living with ‘untreated’ PC. The similar urinary and sexual function scores reported by the two groups suggest that active surveillance related biopsies do not have a large impact on urinary and sexual function of AS participants.

**Prostate Cancer**

**P034**

**Reexpression of CRHBP following 5-aza-2’ treatment and alteration of invasion characteristics in cell lines of clear renal cell carcinoma**

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**Introduction & Objectives:** Significance of Urocortin (Ucn or UcnI), UcnIII and their receptors; Corticotropin Releasing Factor Receptor 1 and 2 (CRFR1 and CRFR2), and the binding protein; Corticotropin-Releasing Hormone-Binding Protein (CRHBP) in oncology is growing rapidly. CRF system in human includes Ucn, and Ucn3, CRFR1 and CRFR2, and CRHBP. Expression and pathophysiological implication of CRF system in several different human cancers has been thoroughly reviewed. Recently, we reported the mRNA expression loss and DNA hypermethylation of CRHBP and its correlation with aggressiveness of tumor in clear cell renal cell carcinoma (cc-RCC). However there is no data available about silencing of CRHBP gene and a possible functional role of CRHBP in invasiveness in kidney cancer. The objective of our study was to ass the silencing profile of CRHBP and showing its possible role in invasiveness in kidney cancer.

**Material & Methods:** mRNA analysis of four cell lines (A498, ACHN, RCC-GS, RCC-HS) before and following treatment of cells with 5-aza-2′-deoxycytidine (5-AZA) were carried out. Cells were incubated on days 2–4 with normal medium complemented with 0.125μM 5-AZA and allowed to recover during days 5–8 incubation in normal medium. Real-time impedance analyses of cells grown upon microelectrodes were applied to measure possible effects of CRHBP on proliferation and invasiveness of cancer cells.
Results: Analysis of four cell lines showed that the degree of relative methylation is reduced and mRNA expression concurrently increases between 50 and 150 fold following treatment of cells with 5-aza-2′-deoxycytidine (5-AZA). Inverse relationship of CRHBP CGI methylation and relative mRNA expression levels in renal cancer specimens indicates epigenetic silencing (P < 0.0001). We found, that CRHBP-suppression may substantially affect the invasiveness of RCC cell lines. RCC-GS, derived from a metastatic primary tumor, showed a significantly increased capability to pass a 2.5% matrigel-layer used as a measure for invasiveness (p < 0.001). Corresponding analyses for RCC-HS as a model for a localized cancer and 786-O demonstrated no significant changes vs. the controls in invasion characteristics.

Conclusions: For the first time we showed a functional analysis, confirming the silencing of CRHBP gene in cc-RCC. Inverse relationship of CRHBP CGI methylation and relative mRNA expression levels in renal cancer specimens indicates epigenetic silencing. Moreover Real-time impedance analyses could show a significant role of CRHBP in invasiveness of tumor in CC-RCC.

P035
PSA density: A new dimension “the Prostatocrit”
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Introduction & Objectives: We propose using the zones of the prostate, their individual volumes, the differences in the amount of glandular acini, and hence the relative contribution each makes to PSA production. We have a peripheral zone acinar volume (PZav) and density (PZad). Used with the ratio to the whole gland, we can better predict cancer of all grades and high grade only. We can potentially model the gland as it ages in terms of each zone, into its acinar and stromal elements. This new “prostatocrit” model could offer more accurate nomograms for biopsy. The elucidation of the natural history of BPH and the better prediction of who should have surgery and how patients respond to drugs?

Material & Methods: 674 patients TRUS and biopsy. Whole gland and zonal volumes documented. Glands comprise 70% of prostatic mass.

The WGv × 0.7 yields whole gland acinar volume.
1 – WGav yields whole gland stromal volume.

We compared the use of ratio and acinar volumes when added to a “clinic” model using traditional PSA density.
0.8 × PZv yields the peripheral zone acinar volume.
1 – PZav yields the peripheral zone stromal volume.
The WGav – PZav yields the transition zone acinar volume.
1 – TZav yields the transition zone stromal volume.
The serum PSA is divided into WGav to yield the whole gland acinar density. The peripheral zone acinar density is arrived at by multiplying the WGad times the ratio of the PZav/WGav. The transition zone acinar density is WGad – PZad.

Univariate logistic regression was used to find significant predictors for all grades of cancer and high grade (Gleason 7 and above). Backwards multiple logistic regression was used to generate ROC curves comparing the new model to conventional density and to PSA alone.

Results: Prediction of all grades of prostate cancer: Significant predictors: previous negative biopsy; rectal examination; log peripheral zone acinar density; age. Prediction of high grade prostate cancer: Significant predictors: previous negative biopsy; rectal examination; log peripheral zone acinar density; age.

<table>
<thead>
<tr>
<th>Model</th>
<th>AUC</th>
<th>P-value</th>
</tr>
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<tbody>
<tr>
<td>Acinar model</td>
<td>0.774</td>
<td></td>
</tr>
<tr>
<td>Clinic model</td>
<td>0.745</td>
<td></td>
</tr>
<tr>
<td>PSA model</td>
<td>0.636</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: There is a real use for the ratio and for the “acinar” density in predicting cancer and modelling benign growth. The Prostatocrit outperforms any of the conventional density measurements.

P036
Comparison of zonal growth dynamics of the benign and malignant prostate
S. Robinson, A. Rao, M. Laniado, B. Montgomery. Wexham Park Hospital, Dept. of Urology, Slough, Berkshire, United Kingdom

Introduction & Objectives: We have developed a “prostatocrit” logistic regression model using the differing zones of the gland and their asymmetry of acini to significantly better predict cancer from the benign gland on TRUS biopsy. This model using acinar bulk and PSA and outperforms all conventional forms of PSA densities. We now apply it to suspected differences in growth of prostatic zones, for benign or malignant processes schematic diagram of prostate growth with variation in zones and acinal density.

Material & Methods: We have looked at 819 patients. 672 had TRUS and biopsy, 147 radical surgery. We compare the differences in
1. Zonal and whole gland (WGv) growth rates, transition (TZv) and peripheral (PZv).
2. Acinal volume and stromal volume growth rates (we also compared symptoms (IPSS) and zonal growth).
We compare these with 147 patients who had radical prostatectomy.
Results: See the tables.

<table>
<thead>
<tr>
<th></th>
<th>BPH (n = 409)</th>
<th>All prostate cancer (n = 263)</th>
<th>Radical prostatectomy (n = 147)</th>
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</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>63</td>
<td>68</td>
<td>62</td>
</tr>
<tr>
<td><strong>PSA</strong></td>
<td>8.1</td>
<td>16.4</td>
<td>7.5</td>
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<tr>
<td><strong>IPSS</strong></td>
<td>10</td>
<td>11</td>
<td>11</td>
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<tr>
<td><strong>Volumes (cc)</strong></td>
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<tr>
<td>WGV</td>
<td>57.6</td>
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<td>42.8</td>
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</tr>
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<td>TZv</td>
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<td>13</td>
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<tr>
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<td>9.3</td>
<td>7.6</td>
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<td>1.2</td>
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<td>26</td>
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</tr>
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Slopes univariate linear regression cc/year

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<tbody>
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<tr>
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Slopes densities ng/ml/cc/year

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Slopes ratio

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<td>-0.0041</td>
</tr>
<tr>
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<td>-0.00473</td>
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<tr>
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<td>-0.004</td>
<td>-0.00276</td>
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<tr>
<td>Tzv/WGV</td>
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<tr>
<td>Tzv/WGsv</td>
<td>0.0035</td>
<td>0.004</td>
<td>0.00275</td>
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Conclusions: Benign patients are younger with bigger transition zones. PZ same size in all three groups. Once the PZ reaches its mature volume it does not grow much more after this. PZ/TZ increases with cancer and great PZ acini growth and less TZ stroma growth.

TZ stroma increases with benign tissue and this was the sole predictor of PSA on multivariate analysis along with age. The IPSS score increases more with TZ growth than with PZ growth. Ratio of volumes reflects large positive increases in TZ volumes, acinal/stromal, relative to whole gland with benign glands. Negative ratios with the peripheral zone being outgrown by transition zone in all three groups. This offers useful insight into the different growth rates of benign and cancersous glands.

P037
In vitro study on radiation-induced abscopal effect in prostate adenocarcinoma

S. Tubin, M. Valeriani, S. Bracci, E. Clarke, R. Maurizi Enrici. Sant'andrea Hospital, Dept. of Radiotherapy, Roma, Italy

Introduction & Objectives: This in vitro study evaluated the ability of prostate adenocarcinoma (ADC) cells to generate the radiation-induced abscopal effect (RIAE) exploring the factors that may affect its intensity and quality (type). The idea was to produce a strong, clinically applicable RIAE, that could lead to development of innovative approaches in modern radiotherapy of prostate cancer, especially for those patients with hormone-refractory ADC in which radiotherapy might have a limited role.

Material & Methods: 2 human prostate ADC cell lines, PC-3 hormone-resistant and DU-145 hormone-sensitive, have been irradiated using wide range of doses (15, 50, 200, 500, 1000, 2000 and 3000 cGy in 1 fraction) to obtain radiation-conditioned medium (RCM) which was then used to “treat” the unirradiated cells and to evaluate the cytokines levels (Eotaxin, IFN-γ, IL-2, IL-4, IL-6, IL-8, IL-12, MIP-1-α, TNF-α and VEGF) as possible mediators of this phenomenon. Using a spectrophotometer cell growth was assessed. All comparisons were made to the negative control using paired t-tests. Significance was set at p-value <0.05, 2-tailed test.

Results: Both cell lines were able to induce RIAE observed as a significant reduction of index of cellular proliferation (Figure 1). RIAE was induced with all doses used in experiment and was of anti-proliferative type. No RCM induced increased cellular proliferation. RIAE intensity depended on dose and tumour differentiation grade: The strongest RIAE for PC-3 was achieved with 2000 cGy while for DU-145 with only 15 cGy. After induction of abscopal effect significant increase in concentration level was recorded for 7 out of 11 cytokines evaluated, but among them only IL-6 correlates with strongest RIBE in PC-3.

Conclusions: RIBE intensity can be manipulated by modifying radiation dose and depends on differentiation grade. IL-6 correlates with strongest RIBE after exposure of PC-3 to a very high dose of radiation.
high dose of radiation thus indicates its possible involvement in bystander signals transmission.

**P038**
In vivo visualization of rat leukocytes redistribution upon pelvic irradiation

F. Benigni1, C. Cozzarini2, C. Sini3, A. Spinelli3, M. Venturini4, L. Perani5, V. Sacco5, A. Viale6, A. Capelli7, A. Mondino8, A. Briganti9, M. Bellone9, C. Fiorino9, R. Calandrino9, L. Perani5, V. Sacco2, A. Viale2, A. Capelli2, A. Mondino6, A. Briganti2, M. Bellone9, C. Fiorino3, R. Calandrino3.

**Introduction & Objectives:** Decrease in the peripheral blood leukocyte count is a well-known side effect of radiation therapy for prostate cancer and it is considered a negative prognostic factor. Beside the direct toxicity to the bone marrow, a redistribution of circulating leukocytes after pelvic irradiation is also a relevant factor, which is still poorly investigated.

**Material & Methods:** We have set up an animal model to allow tracking of peripheral leukocyte relocation after radiation treatment focused to the urinary bladder. This method will serve to investigate a possible selective accumulation of circulating leukocytes to specific anatomical districts affected by the radiations. Fisher female rats (n=6) were adoptively transferred IV with 4×10⁷ VivoTag-750-labelled syngeneic primary splenocytes, two hours before bladder irradiation. Animals were transurethrally catheterized to allow contrast agent instillation and undergone to a kV cone beam computed tomodraphy (CBCT) imaging to precisely deliver monofraction radiation treatment (15–25 Gy range). Bladder tissue reaction to the radiation was followed over time by ultrasonography, while possible accumulation sites of labelled leukocytes were evaluated by in vivo fluorescent imaging.

**Results:** Preliminary results show that a significant increase in the bladder wall thickness peaked 4 days after radiotreatment in animals treated at a dose of 25 Gy. A fluorescent signal, secondary to labelled splenocytes accumulation, was detectable in the liver and lymph nodes of all adoptively transferred rats, 2 and 6 days after transfer, as expected. A modest specific signal (30% increase) at the bladder level was detected only in animals (n=2) subjected to 25 Gy irradiation (Figure 1a), when compared to the non-irradiated controls (n=3) (Figure 1b). No specific fluorescent signal was detected at the bladder levels in animals treated with 20 and 15 Gy (n=2/group).

**Conclusions:** These data suggest that relocalization to the damaged tissue of peripheral leukocytes can be followed in a non-invasive way and may occur dependently on the radiation dosage. Further analyses are currently ongoing.

**P040**
ARAMIS trial: Efficacy and safety phase 3 trial of ODM-201 in men with high-risk nonmetastatic castration-resistant prostate cancer

K. Fizazi1, N.D. Shore2, T. Tammela3, T. Sarapohja4, A. Vuorela5, I. Russ6, A. Snapir7, M.R. Smith8, 1Institut Gustave Roussy, University of Paris Sud, Dept. of Cancer Medicine, Villejuif, France; 2Carolina Urologic Research Center, Dept. of Urology, Myrtle Beach, South Carolina, United States of America; 3Tampere University Hospital, Dept. of Urology, Tampere, Finland; 4Orion Corporation Orion Pharma, Biostatistics and Support Functions, Espoo, Finland; 5Orion Corporation Orion Pharma, Development, Turku and Espoo, Finland; 6Bayer Pharma AG, Global Clinical Oncology, Berlin, Germany; 7Massachusetts General Hospital, Dept. of Hematology/Oncology, Boston, Massachusetts, United States of America

**Introduction & Objectives:** There is no standard treatment for nonmetastatic castration-resistant prostate cancer (nmCRPC) besides continuing androgen deprivation therapy (ADT). Preventing metastatic disease in nmCRPC is a major unmet need. Patients with nmCRPC who have shorter prostate-specific antigen (PSA) doubling time (PSADT) are at high risk for metastatic disease or death (Smith et al. J Clin Oncol. 2013;31:3800–3806). ODM-201, a novel second-generation oral androgen receptor inhibitor, has shown an excellent safety profile and promising anticancer activity in progressive CRPC (Fizazi et al. Lancet Oncol. 2014;15:975–985). The ARAMIS trial aims to evaluate the efficacy and safety of ODM-201 in high-risk nmCRPC.

**Material & Methods:** This international, randomized, double-blind, placebo-controlled phase 3 trial (NCT02200614) involves over 300 sites in more than 30 countries. 1500 patients on ADT will be randomized 2:1 to ODM-201 600 mg or placebo twice daily. Patients will be stratified by PSA and baseline level of a bone-targeting agent. Eligibility criteria include nmCRPC, PSADT ≤10 months, and screening PSA ≥2 ng/mL. Endpoints will be analysed using a stratified log-rank test, accounting for stratification. The trial has 90% power to detect a target hazard ratio of 0.75 based on a 2-sided log-rank test at an overall significance level of 0.05. Kaplan–Meier estimates will be produced for both treatment groups.

**Results:** The primary endpoint is metastasis-free survival based on central independent review of bone scan and CT/MRI every 16 weeks; progression of regional disease is not considered metastasis. Secondary endpoints are overall survival, time to first symptomatic skeletal event, initiation of first cytotoxic chemotherapy for prostate cancer, and pain progression. Additional endpoints are progression-free survival, time to first prostate cancer-related invasive procedure, initiation of subsequent antineoplastic therapy, PSA progression, change in ECOG status, and changes in health-related quality of life.

**Conclusions:** The ARAMIS trial is open and recruiting, with the first patient randomized in October 2014.
041 Molecular characterization of the Engrailed-1 and -2 variants of the family of the homeodomain genes in human prostate cancer: Potential value as biomarkers
E. Gomez Gomez1, D. Hormaechea-Agulla2, J. Carrasco-Valiente1, J. Valero-Rosa3, A. Ibáñez-Costa4, M. Moreno5, M. Gañete5, J. Castaño1, M. Requena-Tapia1, R. Luque1. 1Reina Sofia University Hospital/IMIBIC. Dept. of Urology, Cordoba, Spain; 2Reina Sofia University Hospital/IMIBIC, Cordoba, Spain; 3Reina Sofia University Hospital/IMIBIC, Dept. of Anatomical Pathology, Cordoba, Spain

Introduction & Objectives: Prostate cancer (PC) is the most common malignancy in the male population however; molecular diagnostic/prognostic markers that better define this pathology are very limited and frequently found to be unspecific (i.e. PSA). Therefore, it is necessary to provide new clues for novel diagnostic/prognostic/therapeutic targets in this pathology. Some genes belong to a family of homeodomain-containing transcription factors that determine cell/tissue identity during normal embryonic development which, have been shown to be re-expressed by different tumoral cell-types. Interestingly, some studies have indicated that the enrafted variants (EN1 and EN2) might be used as a potential diagnostic markers of early PC however; these few studies are conflicting and incomplete and, to date, limited information is available concerning the presence of these variants in PC-cells. Therefore, the main goals of this study were to analyse the expression levels of EN1- and EN2-variants in PC-tissues and cell lines and, to determine urinary levels of EN2-variant in patients with and without PC.

Material & Methods: To that end, we implemented a triple strategy by using: 1) paraffin-embedded PC-tissues obtained from radical prostatectomies and its adjacent normal-control tissues; 2) normal and androgen-dependent (LnCaP/VCaP/22Rv1) and androgen-independent (DU145/PC3) PC-cell lines and; 3) Urinary fluids from patients with PC and control-patients.

Results: Expression of EN2-variant, but not EN1-variant, was up-regulated in PC-tissues compared to normal-adjacent tissues (p < 0.05). Moreover, EN1/EN2-variants were not expressed in a normal-prostate cell-line while, EN2-variant was over-expressed in all PC-cells lines analyzed (LnCaP > DU145 > VCaP > PC3 > 22Rv1). Interestingly, only DU145 cells expressed EN1-variant. Median urinary levels of EN2-variant collected from PC and controls-patients without prostate massage were similar (~0.8 ng/ml).

Conclusions: Altogether, our ongoing studies suggest a potential role of EN-variants, especially EN2, in PC cells. Therefore, additional experiments are planned to determine the functional role of these EN-variants in PC-cells as wells as, additional measures of urinary and plasma EN2 levels in PC and control patients following a prostate massage.

Funding: PI13–00651, PI-0639–2012, BIO-0139, CTS-1406, MedCom, Darmstadt, Germany

Keywords: Prostate Cancer, Engrailed-1 and -2 variants, diagnostic/therapeutic markers

042 A phantom validation study of an MRI-TRUS fusion device for targeted prostate biopsy
O. Wegelin1, K. Henken2, D. M. Somford3, F.A.M. Breuking4, J.L.H.R. Bosch1, C.P.F. Van Swol2, H.E.E. Van Melick2. 1St Antonius Hospital, Nieuwegein, The Netherlands; 2St Antonius Hospital, Dept. of Physics and Instrumentation, Nieuwegein, The Netherlands; 3Canisius Wilhelmina Hospital, Dept. of Urology, Nijmegen, The Netherlands; 4St Antonius Hospital, Dept. of Radiology, Nieuwegein, The Netherlands

Introduction & Objectives: This study aims to evaluate the ex vivo accuracy of a perineal MRI-TRUS fusion device (BiopSee®).

Results: The accuracy of the system was evaluated using a 3D ultrasound phantom containing anatomical and pathological features. The system was tested using an 18-G biopsy needle with a needle diameter of 0.8 mm. The accuracy of the system was evaluated in a 3D plane, where the average targeting error (TE) was 0.4 mm. The overall accuracy of the system was 95% for lesions with a maximum diameter of 3 mm or more. In 3D, the accuracy was 61% for lesions with a maximum diameter of 3 mm or more. In vivo, the accuracy was 94% for lesions with a maximum diameter of 3 mm or more. In 3D, the accuracy was 61% for lesions with a maximum diameter of 3 mm or more.

Conclusions: This phantom study demonstrates that the accuracy of the system is 94% for lesions with a maximum diameter of 3 mm or more. In vivo, the accuracy was 94% for lesions with a maximum diameter of 3 mm or more.

043 Accuracy of kallikrein testing (4K) in prostate cancer detection and grading. A preliminary prospective study
F. Clar1, L. Morell2, J.M. Tenías3, J. Lopez1, E. Morán1, C. Ferrandis1, R. Canó2, P.L. Estela4. 1Hospital De La Ribera, Dept. of Urology, Alzira Valencia, Spain; 2Hospital De La Ribera, Dept. of Pathology, Alzira Valencia, Spain; 3EVES, Valencian School for Health Studies, Valencia, Spain; 4Hospital De La Ribera, Biochemical Laboratory, Alzira Valencia, Spain

Introduction & Objectives: The kallikreins are a group of 15 homologous secreted serine proteases that have been shown to be elevated in prostate cancer. The accuracy of kallikrein testing in prostate cancer detection and grading is still under investigation. This study aims to evaluate the accuracy of kallikrein testing in prostate cancer detection and grading.
to be involved in many aspects of carcinogenesis. The human prostate secretes 4 kallikrein. The Kallikrein 3 is better known as Prostatic Specific Antigen (PSA). A panel of four kallikreins made up by PSA, free PSA, intact PSA and human Kallikrein 2 (4K) discriminates between men with indolent carcinoma disease and aggressive carcinoma disease.

To determine the accuracy of 4K testing to differentiate prostatic benign from malignant processes as well as to identify cutoff levels that allow discriminating between low grade and high grade prostate cancer.

**Material & Methods:** 10 ml of blood was drawn, prior to trans-rectal ultrasonography guided biopsy to 50 patients with high serum PSA. 7 of them with an abnormal digital rectal examination (DRE), and sent to a reference hospital to perform the 4K test. The prostate core biopsies were performed following the Vienne protocol obtaining a minimum of 12 samples from each case which were processed as usual in the Pathology Department. The levels of 4K tests matched to the pathological diagnosis were used to determine the cutoff levels.

For the statistical analysis: We used the ANOVA test or its equivalent non-parametric equivalent Kruskall Wallis test. We determined the Area Under ROC curve (AUC) and its 95% confidence interval for difference cancer or no cancer and for establish difference between low grade and high grade prostate cancer. Moreover, we have explored several cutoffs depending on its high specificity (Snout: Sensitivity rules Negatives out) and sensitivity (Snout: Sensitivity rules Negatives out).

**Results:** The median age of the patients was 64.6 years (range 45 to 85). In 21 of them (42%) prostatic carcinoma was diagnosed. The median level of PSA was 11.6 ng/ml (range 3.1–45.3); the PSA\textsubscript{total}/PSA\textsubscript{free} in 32 patients (64%) was between 0.01 and 0.13, in 15 patients (30%) was between 0.16 and 0.25 and in 3 patients (6%) was over 0.25. The percentage of 4K test ranged between 0 and 100% with a median of 30.5% and quartiles 1 and 3 were 10.8 and 58% respectively. We found statistically significant differences related to pathological features, mainly the number of cores and percentage of them involved by carcinoma. The AUC of 4K Test for discrimination carcinoma of the prostate was 0.91 (CI 95% 0.83–0.99) Between prostatic cancer Gleason Score 6 or Gleason ≥7 the AUC was of the 4k 0.81 (CI 95% 0.58–1). When the 4k test was between 12% and 29.5% was the range for prostatic carcinoma whith a Gleason score (3+3) 6.

**Conclusions:** The 4K test discriminates between benign pathology and malignant diseases better than PSA alone. We could establish two cutoff points, one of 12% for absence on neoplasia and one of 29.5% determining high grade prostate carcinoma. The 4K test could be useful in the identification of prostatic cancer patients.

**P045**

**The association of male pattern baldness and risk of cancer and high grade disease among men presenting for prostate biopsy**

G. M. A. Al-Edwan, B. Bhindi, A. Finelli, A. Zlotta, J. Trachtenberg, N. Fleshner, University of Toronto, Princess Margaret Hospital, Dept. of Urology, Toronto, Canada

**Introduction & Objectives:** Androgens have been implicated in both male pattern baldness (MPB) and prostate cancer. We set out to prospectively determine if men with independently assessed MPB are at higher risk for prostate cancer at biopsy and determine if any grade associations exist. To determine if men with MPB are at higher risk for PCA development and if any grade associations exist.

**Material & Methods:** We prospectively enrolled 394 eligible patients presenting for prostate biopsy and independently determined their MPB pattern using the validated Norwood classification (0: no balding; 1 frontal balding; 2 mild vertex balding; 3 moderate vertex balding; 4 sever vertex balding) system univariate and multivariable models including Norwood score, age, prostate specific antigen and digital rectal examination abnormalities were calculated for the outcomes of cancer and high grade disease (Gleason more than 6). C-statistics analysis of our models were then compared with and without MPB pattern for marginal utility.

**Results:** On univariate analyses, Norwood patterns were increasingly associated with cancer and high-grade disease with a dose-effect (P for trend < 0.0001 for cancer and P = 0.0036 for high grade disease). On multivariable analyses, trends still held with all patients exhibiting Norwood scale 2 or higher at increased risk factor for cancer. In predicting risk of high-grade disease, only patients with Norwood pattern 4 exhibited an increased risk.

**Conclusions:** MPB appears to be a strong and independent risk factor for both cancer and high grade disease for men presenting for prostate biopsy. OR’s are superior to marketed costly genetic tests. Further research is needed to understand the biology behind this observation and to incorporate these findings into clinical decision making.
**P046**  
A Phase 3 study of enzalutamide in non-metastatic (M0) Castration-Resistant Prostate Cancer (CRPC) patients

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¹RWTH University Aachen, Dept. of Urology, Aachen, Germany; ²San Camillo and Forlanini Hospitals, Dept. of Oncology, Rome, Italy; ³Institut Gustave Roussy, University of Paris Sud Villejuif, France; ⁴University of Montreal, Dept. of Urology, Montreal, Canada; ⁵Carolina Urologic Research Center, Dept. of Urology, Myrtle Beach, United States of America; ⁶Medivation Inc., Dept. of Clinical Development, San Francisco, United States of America; ⁷Astellas Pharma Global Development, Leiden, The Netherlands; ⁸Medivation Inc., Dept. of Biostatistics, San Francisco, United States of America; ⁹Medivation Inc., San Francisco, United States of America; ¹⁰University of Michigan, Dept. of Urology, Ann Arbor, United States of America

**Introduction & Objectives:** Prostate cancer growth is dependent on androgen receptor (AR) signaling. There is no pharmacotherapy approved for patients with M0 CRPC and most patients will eventually develop metastatic disease despite ongoing androgen deprivation therapy (ADT). In a recent study, patients with a PSA ≥8 ng/mL or PSA doubling time of ≤10 months had a median time to bone metastasis of only 2 years (Smith et al. Lancet 2012; 379: 39–46). Enzalutamide is an oral AR inhibitor that targets multiple steps in the AR signaling pathway. In two large Phase 3 studies (Scher et al. NEJM. 2012; 367: 1187–1197, Beer et al. NEJM. 2014; 371: 424–433) enzalutamide was shown to prolong overall survival and radiographic progression-free survival in patients with metastatic CRPC. In the STRIVE Phase 2 study, enzalutamide was shown to prolong progression-free survival in patients with M0 and M1 CRPC compared to bicalutamide (Penson et al. AUA 2015). The objective of the PROSPER trial is to evaluate the efficacy and safety of enzalutamide in M0 CRPC patients.

**Material & Methods:** PROSPER is a randomized, double-blind, placebo-controlled, Phase 3 study (NCT02003924) initiated in December 2013 and involving more than 250 sites in the United States, Canada, Europe, South America, and the Asia Pacific region. Eligibility criteria include: asymptomatic M0 CRPC; PSA doubling time ≤10 months; screening PSA ≤2 ng/mL; and adequate hematologic, hepatic, and renal function. Approximately 1560 patients will continue ADT and will be stratified 2:1 to enzalutamide 160 mg/day or placebo. Patients will be stratified by PSA doubling time (<6 vs 6–10 months) and baseline use of bone-targeting agent (yes vs no). The primary endpoint is metastasis-free survival based on central independent review of whole-body radionuclide bone scans for bone disease assessment and CT or MRI scans for soft tissue disease assessment. Imaging will be undertaken at screening and every 16 weeks post randomization until radiographic progression. The study has 90% power to detect a target hazard ratio of 0.75 based on a 2-sided log-rank test at an overall significance level of 0.05. Secondary endpoints include: overall survival; time to pain progression; time to opiate use for prostate cancer pain; time to first use of cytotoxic chemotherapy; time to first use of new antineoplastic therapy; time to PSA progression; PSA response; and quality of life as assessed by Functional Assessment of Cancer Therapy for patients with Prostate cancer (FACT-P), EuroQOL-5 Dimension 5 Level version (EQ-5D-5L) and Quality of Life Questionnaire – Prostate module (QLQ-PR25).

**P047**  
Penile metastasis: A rare presentation of prostate cancer

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¹Hospital Santa Maria, Dept. of Urology, Lisbon, Portugal; ²Hospital Santa Maria, Dept. of Pathology, Lisbon, Portugal

**Introduction & Objectives:** Penile metastasis in prostate cancer is a rare condition that usually occurs in a late stage of disease and in association with poor prognosis. The main metastatic spread route is retrograde venous spread. Other mechanisms are lymphatic or arterial spread, direct extension or surgical instrumentation implantation. The main location is the corpora cavernosa, being the glans less affected. Clinical manifestations include urethral bleeding, complete urinary retention, malignant priapism (40%), local pain or palpable nodules. Definitive diagnosis is made by needle core biopsy. Treatment should be seen with palliative intention and improvement of quality of life. Treatment options are local excision, partial or total penectomy, bilateral orchiectomy, radiotherapy, hormonal and/or chemotherapy.

We present a case of penile metastasis in a 77 years old man with prostate adenocarcinoma, PSA 301 ug/L and Gleason score 9 (4+5).

**Material & Methods:** Patient underwent bilateral orchiectomy. Intraoperatively, identification of a palpable nodule in the glans, with endophytic growth. It was performed a needle core biopsy. The patient started bicalutamide 150 mg daily.

**Results:** Histological confirmation of prostate adenocarcinoma. Immunohistochemistry positive for PSA. 2 weeks later, improvement of general state, PSA 101 ug/L.

**Conclusions:** Penile metastasis in prostate cancer is a rare condition, in association with disseminated disease and poor prognosis. A 6-month mortality of 80% and an average survival of 1 year after initial lesions. Definite diagnosis is histological. Treatment should be seen with palliative intention and options depending on patient general state, location and extension of primary tumour, presence of metastasis and symptoms. Penectomy is to be considered in patients with ulceration, irritating secretion, intractable pain for symptom control.

**P048**  
Detrimental effect of preoperative neoadjuvant androgen deprivation in node-negative patients treated with radical prostatectomy and adjuvant RT

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**Introduction & Objectives:** To investigate a possible detrimental role of neoadjuvant hormonal therapy (NEOHT) prior to radical prostatectomy (RP) in a single-Institute cohort of 513 node-negative patients (pts) treated with RP and adjuvant radiotherapy (ART) followed for >10 years.

**Material & Methods:** From 1993 to 2009, 513 pT2–pT4, R0/R1, pN0 (on a median of 13 LN) pts underwent ART after a median of 3.4 months from RP owing to surgical margin (SM) infiltration and/or extracapsular extension (ECE) with either conventionally- or hypofractionated regimens. The 2-Gy equivalent (EQD2) median dose delivered to the prostate bed was 67.4 Gy (range 53.57–76.40). Sixty-four pts (12.5%) received prophylactic WPRT.
Prior to RP, 166 pts (31%) had received NEOHT for a median of 3 months (range 1–18). The 2 cohorts, NEOHT_no (NEOHTN) and NEOHT_yes (NEOHTY) were comparable with respect to median FU (121 vs 126 months), Gleason score (GS) 7–10 (65 vs 69%), GS 8–10 (18 vs 20%), SM+ (62 vs 69%), use of AAD (23 vs 31%, p=0.052) but not in terms of iPSA (9 vs 13 ng/mL), pT≥3b (30 vs 44%) and AAD length (mean 15 vs 22 months).

Results: At Cox univariable analysis, pT≥3b and NEOHT were the only 2 covariates always predictive of significantly reduced biochemical relapse-free (bRFS), disease-free (DFS, local and/or distant failures), distant metastases-free (DMFS), overall (OS) and cancer-specific (CSS) survival. The 10-year bRFS, DFS, DMFS, OS and CSS in NEOTHN and NEOHTY were: 78 vs 60%, 89 vs 82%, 92 vs 80%, 92 vs 81% and 98 vs 92%, respectively, p-value always ≤0.01. An ROC curve analysis indicated distinct "most informative cut-offs" for NEOHT length (from ≥1 to ≥3 months) with respect to different end-points (Table 1). Variables with a p-value.

Conclusions: Though weakened by its retrospective nature and an uneven distribution of some prognostic variables, this analysis highlights a significant detrimental role of NEOHT in pNO pts treated with RP and ART, possibly through a neuroendocrine differentiation induced by NEOHT.

**P049**

A new approach for an improved PSA doubling time computation for selecting patients candidate to timely salvage radiotherapy for a biochemical recurrence after prostatectomy

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Introduction & Objectives: PSA doubling time (PSADT) has a recognized prognostic role in patients (pts) candidates to salvage radiotherapy (SRT) for a biochemical recurrence (BR) after radical prostatectomy (RP). Nevertheless, its computation relies only on few measurements of a single patient thus it might result inaccurate. The aim of this analysis was to develop a new approach for a more accurate PSADT computation.

Material & Methods: The study included 303 node-negative patients who undertaken RP between 1994 and 2015. For 200/303 patients, we had data of the follow-up after SRT for BR after RP. BR was defined as the first of two or more consecutive and increasing PSA values >0.20 ng/mL after RP. The biochemical relapse-free survival (bRFS) after SRT was defined as the time from the beginning of SRT to PSA failure after SRT (i.e. a single PSA ≥0.20 ng/mL after an SRT-induced nadir or an increase of serum PSA despite SRT).

PSADT computation was based on an increasing set of hormone-naïve PSA starting from the first PSA ≥0.10 ng/mL up to the beginning of SRT. The standard PSADT (S-PSADT) was computed in the usual way with the data of a single patient. The new approach for PSADT computation (N-PSADT) relied on a linear mixed-effects model (LME) with the coefficients of the fixed effects estimated using the data of a sample of patients. We robustly selected the covariates in the model with a resampling procedure based on backward selection. For evaluating the new approach, the dataset was randomly divided in a training and test set with 2/3 and 1/3 of the patients. The LME model was estimated on the training set and then the N-PSADT was computed for each patients in the test set. The Wilcoxon test was used to compare the two methods with respect to the mean square error (MSE) between the predicted and observed last PSA measurements (without using these ones for computing the PSADTs). We evaluated the ability in predicting the 5-yr bRFS after SRT with ROC curve analysis.
Results: In the LME model analysis on the training set, the PSA post RP resulted to be a significant predictor of the longitudinal trend of the PSA. The new model achieved a significantly lower MSE for predicting the PSA in the test set (0.014 vs 0.178, p < 0.0001). In the test set, only 13 pts experienced BR after SRT within 5-years, among the 43 pts with these data. At ROC analysis S-PSADT obtained an AUC = 0.667, with an optimal cut-off giving sensitivity = 0.62 and specificity = 0.70. The N-PSADT achieved an AUC = 0.703, with an optimal cut-off giving sensitivity = 0.62 but a higher specificity = 0.77.

Conclusions: This preliminary study shows a new promising approach for PSADT computation, which improves PSA prediction and increases the specificity for 5-yr bRFS prediction.

P050
Assessing cancer risk in 29 MHz micro-ultrasound images of the prostate: Creation of the PRI-MUS (prostate risk identification using micro-ultrasound) protocol

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Introduction & Objectives: Conventional transrectal ultrasound (TRUS) biopsy is performed using a needle guide (TRUS) for guiding prostate biopsies. We have developed a novel high resolution micro-ultrasound system (29 MHz) to image and target prostate cancer during transrectal biopsies. The purpose of this study is to establish a protocol (PRI-MUS, or prostate risk identification using micro-ultrasound) for standardizing analysis of prostate images from the micro-ultrasound system. PRI-MUS includes an evidence-based scoring system to assess the risk of prostatic carcinoma.

Material & Methods: Cine loops of 200 transrectal ultrasound-guided (TRUS) biopsies were examined from an ongoing multi-center clinical trial of high-resolution TRUS vs standard TRUS for detection of clinically significant prostate cancer using the novel 29 MHz ExactVu™ system (Exact Imaging, Toronto, Canada). Subjects were undergoing TRUS biopsy for suspicion of cancer due to PSA elevation and/or abnormal DRE. Investigators used the initial image set, with pathology results available, to agree on standardized features to describe each image. A further 200 cine loops from the same trial were then read by the same investigators but blinded to pathology to assess correlation with biopsy results. An independent set of 100 cine loops, again blinded to pathology, was used for validation. 3 of the 5 investigators who performed this blinded validation were familiar with the ExactVu™ system but naïve to the PRI-MUS protocol and received only 1 hour of PRI-MUS training.

Results: Ten sonographic features associated with pathologically confirmed malignant or benign tissue were identified during initial review; 6 were significant when tested on the blinded data set. These features were incorporated into a 5-level risk scale; from “Very Low” (mean relative risk 0.28) to “Very High” (1.99) risk for clinically significant prostate cancer. Validation results showed an AUC of 0.60±0.02 over 5 independent reviewers. Each reviewer’s ability to detect clinically significant cancer using PRI-MUS was significant at the p < 0.1 level, and overall with p = 0.0001.

Conclusions: The resolution of the micro-ultrasound platform, paired with the PRI-MUS protocol, shows significant promise in aiding real-time visualization of prostate cancer. This objective and reliable imaging protocol may be useful in facilitating targeted biopsies, with an accuracy similar to that seen historically using only T2-weighted anatomical MRI. This is a first implementation of a risk assessment protocol on high-resolution micro-ultrasound images in men undergoing biopsy for suspicion of prostate cancer and will require ongoing refinement, including expansion to a multi-parametric approach incorporating functional scans for optimal diagnostic accuracy and a more direct comparison with MRI-based PI-RADS.

P051
The incidence and sequela of lymphocele formation after robot-assisted extended pelvic lymph node dissection

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Introduction & Objectives: To reveal an accurate incidence of lymphocele formation and its sequelae following robot-assisted radical prostatectomy and eLND in a contemporary prostate cancer cohort.

Material & Methods: Consecutive patients who underwent radical prostatectomy and eLND with robot-assistance and had a minimum follow-up of 3 months were included. All surgeries were performed by one surgeon (ABK) through a transperitoneal approach with patients uniformly receiving low molecular weight heparin. Patients were followed with serial ultrasound imaging for lymphocele surveillance. Incidence and sequelae of lymphoceles were retrospectively assessed.

Results: A total of 521 patients were analysed. Follow-up after surgery was 31.3 ± 20.8 months. Lymphocele developed in 9% and became symptomatic in 2.5%. All (except one) were detected on 1st month imaging; however, 76% regressed at 3 month ultrasound. If lymphocele persisted at 3 months, 64% would develop symptoms associated with infection and require drainage. Other symptoms related to lymphocele were rare. Comparisons of patient characteristics among patients who did and did not develop lymphoceles did not demonstrate any significant prognostic indicators to predict the occurrence of lymphocele in neither univariate nor multivariate analysis in the present cohort.

Conclusions: The incidence of symptomatic lymphocele after robot-assisted radical prostatectomy and eLND is rare. Obtaining an US imaging at 3 months after surgery seems feasible. Once a lymphocele is detected on 3 monthly US, discussing percutaneous external drainage with the patient appears to be wise, since it may prevent the development of symptomatic lymphocele in 2/3 of the patients.

P052
Efficacy of abiraterone acetate in chemotherapy-naive patients with mCRPC presenting with visceral disease

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Introduction & Objectives: Abiraterone acetate (AA) prolongs median overall survival compared with prednisone alone of men with metastatic castration-resistant prostate cancer (mCRPC) who are chemotherapy (ct) naïve or who have already received prior ct. Approximately 20% of patients (pts) with mCRPC participating in first-line studies had visceral metastasis (vm) carrying particularly poor prognosis. In exploratory analysis COU-AA-301 on post-docetaxel pts it was shown that vm involvement did not preclude clinical benefit from AA. Clinical data on pts with vm in pre-docetaxel setting are lacking. The aim of this retrospective analysis was to evaluate biochemical, radiographic response and PSA in ct naïve mCRPC pts who presented with vm and received AA as a first line treatment.
Material & Methods: We retrospectively analysed clinical records of mCRPC pts who received AA with methylprednisolone as first line treatment at Oncology Institute Ljubljana between January 2012 and May 2015. Within this group we selected pts with vm. Biochemical response from baselines values (defined as PSA30, PSA decline 30–50%; PSA50, PSA decline ≥50%, and PSA progress, PSA rise ≥25%), radiographic response (PR/CR/SD/progression) according to RECIST and progression-free survival (PFS) were evaluated. SPSS was used for descriptive statistics and survival analysis.

Results: 100 pts with mCRPC received AA in the first line setting, and 13 of them had vm. Most of the pts with vm had primary metastatic disease (58%), Gleason score ≥9 (66%) and had visceral and skeletal metastasis (83%) at treatment initiation. Median follow up was 8.2 mo (range, 0–23.9). Outcomes in the pts with vm are depicted in Table 1. Median PFS in all evaluated pts was 11.2 mo (95% CI 8.6–13.7) and 4.9 mo (95% CI 2.1–7.8) in the subgroup with vm. We observed hepatotoxicity grade 3 in 3/13 pts with vm, two of them having liver metastasis.

Table 1. Biochemical and radiographic response in pts with vm treated with AA plus corticosteroids in first-line setting (n = 13)

<table>
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<tr>
<th>Response</th>
<th>n (%)</th>
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<tr>
<td>PSA response (n = 12/13)</td>
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<tr>
<td>PSA30</td>
<td>1 (8.3%)</td>
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<tr>
<td>PSA50</td>
<td>7 (58.3%)</td>
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<tr>
<td>PSA progress</td>
<td>4 (33.4%)</td>
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<tr>
<td>Radiographic response (n = 6/13)</td>
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<tr>
<td>CR</td>
<td>0</td>
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<tr>
<td>PR</td>
<td>2 (33.3%)</td>
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<tr>
<td>SD</td>
<td>1 (16.6%)</td>
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<td>progress</td>
<td>3 (50.1%)</td>
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</table>

Conclusions: Ct-naive pts with mCRPC presenting with vm may well respond biochemically and radiographically to AA plus corticosteroids. Clinical benefit needs to be evaluated in a larger cohort with longer follow up. Hepatotoxicity in these pts should be carefully monitored.

P054
Survival after biochemical failure in prostate cancer: RECAP database outcomes
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Introduction & Objectives: Patient’s evolution after biochemical failure (BF) is a poor studied parameter. We analyse survival from recurrence, patterns of progression and efficacy of salvage therapies in patients treated with radical or postoperative radiotherapy.

Material & Methods: Multicenter retrospective comparative study of 1.141 pts with BF, treated with radical (909 pts) or postoperative (232 pts) radiotherapy. Data were acquired from the RECAP database (August 1993–December 2013). Clinical, tumoural and therapeutic characteristics were collected. Descriptive statistics, survival estimates determined by Kaplan–Meier and comparisons of survival rates were performed using log-rank test.

Results: Mean time to BF from initial diagnosis was higher in irradiated patients (54.6 vs 36.1 months). Table 1 summarizes the patterns of recurrence and evolutive features. With a median follow-up of 101 months [90–105], the 5-years cause-specific

| Response | n (%)
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<tr>
<td>PSA30</td>
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<td>CR</td>
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<td>progress</td>
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survival was 86.5% without significant differences between groups. Only 162 patients (14%) died of prostate cancer and 31 (2.7%) of second cancer.

16% who underwent prostatectomy and 15% of irradiated patients did not receive treatment after BF. Only 41 patients (4.5%) who underwent radical RT had local salvage treatment (cryotherapy, HIFU or brachytherapy) and 71% received androgen deprivation +/- chemotherapy.

The poorest outcomes were observed in patients who developed BF after adjuvant RT, in patients with persistent elevated PSA after prostatectomy and in cases with high Gleason score.

Conclusions:
- In prostate cancer patients, median survival after BF is fairly long.
- There is no difference in survival in both groups at 5 years.
- Androgen deprivation is the most common treatment after BF.

**P055**

Assessment of corticosteroid-associated adverse events with long-term exposure to low-dose prednisone given with abiraterone acetate to metastatic castration-resistant prostate cancer patients


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Introduction & Objectives: Abiraterone acetate (AA) is the prodrug of abiraterone, which inhibits CYP17A1 and testosterone synthesis and prolongs survival of metastatic castration-resistant prostate cancer (mCRPC) patients. A low dose of prednisone (P) is given when AA is administered to mCRPC patients. Long-term use of moderate-/high-dose corticosteroids (CS) has an established adverse event (AE) profile. We investigated whether long-term use of low-dose P with or without AA led to CS-associated AEs.

Material & Methods: 2267 mCRPC patients in COU-AA-301 and COU-AA-302 received 5mg bid P, representing 2006 patient-years of P exposure. 1333 patients received AA+P. We used an inclusive Standardized MedDRA Queries-oriented approach to identify 112 preferred terms for known CS-associated AEs from both databases. CS-associated AEs during each 3-month exposure interval and across all exposure to P were assessed.

Results: The overall incidence of CS-associated AEs for any P exposure was 25%, 26%, and 23% for all patients, AA+P, and P alone, respectively. The incidence of grade ≥3 CS-associated AEs with any P exposure was 5%, 5%, and 4% for all patients, AA+P, and P alone, respectively. The most common grade ≥3 CS-associated AEs occurring in ≥0.1% of all patients were hyperglycemia (2%), cataract (0.4%), diabetes mellitus (0.4%), gastrointestinal hemorrhage (0.3%), adrenal insufficiency (0.1%), hip fracture (0.1%), melena (0.1%), and osteoporotic spinal compression fracture (0.1%). The overall incidence of weight increase (grade 1 and 2 only) was 4%, 4%, and 5% for all patients, AA+P, and P alone, respectively. Most were grade 1 (3.4%). When assessed by duration of exposure (3-month intervals up to ≥30 months), grade ≥3 CS-associated AEs fluctuated between 1% and 2%, but no discernable trend was observed. The observed change in weight from baseline showed no apparent increase over time.

Conclusions: With more than 2000 patient-years of exposure, low-dose P given with or without AA is associated with an overall low incidence of CS-associated AEs. The occurrence of CS-associated AEs remained low with increased duration of exposure to P.

**P056**

Climacturia after robotic-assisted laparoscopic radical prostatectomy

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Introduction & Objectives: Several sexually side effects are common in patients with prostate cancer underwent radical prostatectomy (RP). Climacturia, orgasm-associated incontinence, occurs in 20–40% of men after RP. In our study we assessed prevalence as well as related factors with this symptom in patients who were undergone robotic-assisted laparoscopic radical prostatectomy (RALRP).

Material & Methods: In a retrospective study, we analysed 100 patients who underwent RALRP in our Hospital from May 2011 to July 2014. Patients with previous non-surgical management, those who needed radiotherapy after surgery and patients without sexual activity or orgasmic function (foreplays, genital stimulation or intercourse) were excluded. Finally, we evaluated 62 patients who were asked about climacturia (frequency, severity) and others parameters such as orgasm quality, incontinence (type, severity) and erectile dysfunction treatment trough telephonic survey. We additionally searched about age, nervous preservation in surgery and post-surgical rehabilitation treatment.

Chi-square analysis and logistic regression were applied to evaluate associated factors.
Results: We assessed 62 patients who underwent RALRP. The mean age was 56 years in climacturia group and 59 in non-climacturia group. The mean follow-up time was 26.65 months and 20.35, respectively. Climacturia was reported by 17.9% of them. Climacturia occurred sometimes in 64% and always in 37% and 81% referred minor leakages and only 19% suffered from plentiful leaks. Quality of orgasms after surgery was indicated as worse in 47%. It was better in 13% and equal in 40%. Orgasm quality was worse in Climacturia group. Urinary incontinence rate was 41%, stress incontinence in all cases. 80% was a minor incontinence and only 7% was classified as severe incontinence. Incontinence was more frequent in Climacturia group (62% vs 38%). 68% of patients was using treatment to obtain an erection. 32% of patients underwent erectile dysfunction rehabilitation with pills immediately after surgery. There was not statistically significant differences between patients with and without climacturia about parameters analysed.

Conclusions: The rate of Climacturia in our series was about 18%, similar than literature. In our study, orgasm quality after surgery was worse in climacturia group without statistically significant differences. Incontinence rate was higher in climacturia group (62% vs 38%), 68% of patients was using treatment to obtain an erection. 32% of patients underwent erectile dysfunction rehabilitation with pills immediately after surgery. A phase 3 randomized, placebo-controlled double-blind study of ARN-509 plus abiraterone acetate in chemotherapy-naive metastatic castration-resistant prostate cancer (mCRPC) E. Efstratiou1, D.E. Rathkopf2, G. Attard2, M. Yu3, T.W. Griffin4, M.B. Todd4, D. Wu5, T. Kheoh6, X. Zhao7, F. Saad8. 1University of Athens, Dept. of Clinical Therapeutics, Athens, Greece; 2Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, Dept. of Oncology and Internal Medicine, New York, United States of America; 3Karolinska Institutet, Dept. of Clinical Oncology-Pathology, Stockholm, Sweden; 4Karolinska Institutet, Dept. of Medical Epidemiology and Biostatistics, Stockholm, Sweden

Introduction & Objectives: The aim of the study was to identify psychosocial predictors of participation in STHLM3. STHLM3 was a prospective trial, evaluating a combination of biomarkers and clinical variables with the aim to develop a risk-based model for prostate cancer testing with better test characteristics than PSA in men aged 50–69 years.

Material & Methods: An invitation to participate in a web-survey was sent to 10,000 men three months before their invitation to participate in the STHLM3 study. The web-survey consisted of four questionnaires assessing prostate cancer specific worry, knowledge about prostate cancer, health behaviour and health related quality of life (HRQOL) as possible predictors of future participation or not in STHLM3. Of the 1,980 questionnaire respondents, 596 (30%) did not attend STHLM3 three months later. These STHLM3 non-participants were compared to the 1,384 participants’ (70%) answer with respect to their responses to the questionnaires.

Results: Men who did not attend STHLM3 expressed feeling less worry and less vulnerable to prostate cancer. For example, when asked “How likely do you think it is that you will develop prostate cancer in the next five years?” 13% of the participants responded “Very low” and 56% responded “Moderate” whereas 43% of the non-participant responded “Very low” and 45% “Moderate” (p < 0.001). There was no difference in “Prostate cancer knowledge” between the two groups. The results showed, however, large deficiencies in prostate cancer knowledge among men in both groups. There were statistically significant between-group differences for four out of six health behaviour scales (“Benefits of prostate testing”, “Barriers to prostate testing”, “Intention to attend prostate cancer testing” and “General health”). Finally, the QLQ-C30 questionnaire measuring HRQOL showed a between group difference, with STHLM3 attendants having a better “Global health” than non-attendants (p < 0.0001).

Conclusions: Prostate cancer worry, some health behaviour aspects and health status/quality of life were identified as predictors of attendance to STHLM3. The study also revealed a large deficiency of prostate cancer knowledge in both study groups. These results are valuable in the planning of future prostate cancer screening.
PO59
Equivalent uniform dose predicts late rectal bleeding in a large pooled population
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Introduction & Objectives: To investigate the dose-response relationship for late rectal bleeding (LRB) after radical radiotherapy (RT) for prostate cancer, in a pooled population resulting from two large prospective multicenter trials: AIROPROS0102 (Fellin et al & R&O 2014) and TOG 03.04 RADAR (Ebert et al. IJROBP 2015).

Material & Methods: Both trials included patients (pts) treated with conventional fractionation 3DConformal-RT. Dose range was between 66–74Gy. Planning data were available for all pts and the toxicity (tox) was prospectively scored using the SOMA/LENT scale, with a minimum follow-up of 3 years. Grade2–3 LRB and grade3 LRB were considered as separate endpoints. The relationship between LRB incidence at 3 years and rectal dosimetry was estimated through the Equivalent Uniform Dose (EUD) calculated using the volume parameter n as derived by 3 previous studies: n=0.23 (EUD023, Rancati et al. R&O 2004), n=0.09 (Michalski et al. IJROBP 2010) and n=0.03 (Rancati et al.R&O 2011). All EUDs were included into logistic models. The presence of grade2–3 acute tox was also considered as a potential clinical predictor and inserted into multivariable models together with EUD. The performance of the models was assessed through discriminative power (AUC, sensitivity, specificity) and calibration plot (slope (m) and R² for plot fitting).

Results: 1264 pts were available: 656 AIROPROS0102 and 608 Trog 03.04 RADAR. Grade2–3 LRB was registered in 192 pts (15.2%), while grade3 LRB was present in 80 pts (6.3%). EUĐ023 was the best predictor of grade2–3 LRB: OR=1.09, AUC=0.65, m=1.01 and R²=0.9, indicating moderate discrimination and very good calibration. Coupling EUĐ023 with presence of acute tox highlighted an important role of consequential injury (OR for acute tox = 1.3) and resulted in improved specificity (0.65 vs 0.6 for a fixed sensitivity of 0.6, AUC=0.65, m=1.0, R²=0.88). EUĐ023 was also the best predictor for grade3 LRB: OR=1.08, AUC=0.64, m=0.99 and R²=0.67. Even in this case acute tox played an important role (OR=2.5, AUC=0.64, m=1.03, R²=0.67).

Figure 1 shows LRB probability as a function of EUĐ023 and of the presence of acute GI tox.

Conclusions: EUD calculated with a volume parameter n = 0.23 was predictive of LRB in the pooled population. This dose metric highlights the importance of the medium-high doses ("dose bath", range: 50–75 Gy). Including presence of acute GI tox allowed improvement in specificity, thus underlining once more the importance of the consequential effect between acute and late phases of radioinduced toxicities.

The study was funded by: AIRC IG16087, Fondazione I.Monzino and NHMRC (300705, 455521, 1006447).

PO60
How bad is the outcome of node positive prostate cancer patients: A matched case analysis between N+ and N0 prostate cancer patients
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Introduction & Objectives: To compare clinical outcome of PC patients with (N+) and without positive Inn (N0) after high dose external beam radiotherapy and androgen deprivation (AD).

Material & Methods: Patients with a follow-up of ≥12 months were eligible. All patients had a pelvic Inn dissection. Patients were treated with primary radiotherapy and 2–3 years of AD. A biological equivalent dose of 80Gy was delivered to the prostate in 38 (N0) or 25 (N+) fractions, with a minimal dose of 45Gy to the pelvic Inn for N+ patients. Matching was based on Gleason score, PSA, T-stage, AD and follow-up time. Kaplan Meier statistics were used to calculate 5-years biochemical and clinical relapse free survival (bRFS and cRFS) and prostate cancer specific survival (PCSS). The impact of N-status, Gleason score, PSA level (≤10 versus >10), T-stage, PSA level (<10 versus >10 and ≤20 versus >20 ng/ml), number of Inn removed (<14 versus ≥14) and number of positive Inn (<2 versus ≥2) on bRFS and cRFS was evaluated in uni- and multivariate analysis (log-rank and Cox-regression). The distribution of clinical relapses was assessed.

Results: One hundred and thirty-eight patients were matched 1:1 (Table 1). Patients with N+ and N0 PC were treated with volumetric arc therapy (VMAT) and intensity modulated radiotherapy (IMRT) respectively.

Five-years bRFS and cRFS for N+ versus N0 PC patients groups were 66±7% versus 78±6% (p=NS) and 73±6% versus 84±5% (p=NS), respectively. None of the evaluated parameters was predictive for bRFS or cRFS. Five-years actuarial PCSS was 92±4% for N+ PC patients versus 94±3% for N0 patients (p=NS). Figure 1 presents the distribution of clinical relapses.

Conclusions: High dose external beam radiotherapy with AD for N+ PC patients results in excellent long term bRFS, cRFS and PCSS, comparable to outcome reported in N0 PC patients.
**Table 1.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Primary setting</th>
<th>P-value</th>
</tr>
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<tr>
<td></td>
<td>VMAT, prim</td>
<td>IMRT, prim</td>
</tr>
<tr>
<td></td>
<td>(N=69)</td>
<td>(N=69)</td>
</tr>
<tr>
<td>Median Age (years)</td>
<td>69 [53–82]</td>
<td>67 [41–79]</td>
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<tr>
<td>Median Follow-up (months)</td>
<td>60 [12–108]</td>
<td>60 [16–112]</td>
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<tr>
<td>Median PSA level (mg/ml)</td>
<td>18 [3–240]</td>
<td>10 [4–100]</td>
</tr>
<tr>
<td>Median number of lnn removed</td>
<td>11±7 [1–34]</td>
<td>12±8 [2–42]</td>
</tr>
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<td></td>
</tr>
<tr>
<td></td>
<td>3 (3)</td>
<td>21 (30)</td>
</tr>
<tr>
<td>LPND</td>
<td>23 (35)</td>
<td>21 (30)</td>
</tr>
<tr>
<td>EPLND</td>
<td>43 (62)</td>
<td>27 (40)</td>
</tr>
<tr>
<td>Median duration of hormonal therapy (months)</td>
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<td>24 [6–84]</td>
</tr>
<tr>
<td>Hormonal therapy</td>
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<td>69 (100)</td>
</tr>
<tr>
<td></td>
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<td>Gleason score</td>
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<td></td>
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<td></td>
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<tr>
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</tbody>
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**Introduction & Objectives:** Evaluate testosterone levels in patients undergoing high dose radical radiation therapy (RT) for prostate cancer and enrolled in a prospective multicenter cohort study (DUE01).

**Material & Methods:** The analysis was limited to the population of patients treated with RT alone (no association with hormone therapy) and with a minimum follow-up of two years after the end of RT.

Testosterone levels were measured before RT and 3, 6, 12, 18, 24 months after the end of RT. The trend of this hormone over time was evaluated considering its ratio with respect to the absolute baseline testosterone value prior to RT. Distributions of the ratios were evaluated using analysis of variance and Wilcoxon test.

The population was also stratified using the following factors: age, dose prescription (2 Gy equivalent, alpha/beta = 3 Gy), RT technique (3DCRT vs modulation techniques), age, smoking.

**Results:** Forty-three patients were included in the analysis. All patients had baseline testosterone levels in the normal range.

The trend of testosterone ratios over time is quadratic (anova, p = 0.009), with evidence of a nadir at 6 months after the end of RT (average ratio 0.75, p = 0.0001) and a recovery of the initial values in 18–24 months (mean ratio 0.98) (Fig. 1a). The trends of the average ratios are significantly different stratifying patients for prescription dose. In particular, the ratios are significantly different at 18 months: 1.2 vs 0.87, ≤76GyEq vs >76GyEq (p = 0.017, Fig. 1b).

**Conclusions:** Significant testosterone decrease after prostate RT was detected, with nadir at 6 months after RT end. For most patients this decrease was temporary with recovery at 18–24 months. Significant correlation with prescription dose >76 Gy-equivalent was found, with patient exhibiting longer recovery times. Prescription dose is probably a surrogate of testicular dose.

The study was supported by the Associazione Italiana Ricerca sul Cancro (AIRC-IG13090).

**P062**

Clinical features of PSA surge in patient with CRPC treated with abiraterone acetate or enzalutamide

**Introduction & Objectives:** The objective of this study was to assess the clinical characteristics and its significance of the post-treatment PSA surge in patients with CRPC receiving newer androgen pathway inhibitors (NAPI, abiraterone acetate or enzalutamide).

**Material & Methods:** Serum PSA levels measured in 112 patients with metastatic CRPC treated with abiraterone acetate or enzalutamide between December 2011 and April 2015 were reviewed. Eligibility criteria was as follows; (1) histologic diagnosis of prostate adenocarcinoma; (3) distant metastasis; (3) documented disease progression during hormone treatment (PCWG 2.0 criteria); and (4) Baseline PSA measured within 3 days before starting NAPi and availability of serial PSA values measured every 4 weeks (±1 week) during chemotherapy.
Results: 98 patients met the eligibility criteria. 38 patients received abiraterone acetate and 60 patients received enzalutamide. 21 patients were docetaxel-naïve and 77 patients received NAPi after failure to docetaxel. Among 98 patients, 29 (29.6%) patients achieve a PSA response and additional 27 (27.6%) patients achieved PSA stabilization up to 12 weeks (PCWG criteria). PSA surge developed in 5 patients: 5.1% of all patients and 11% of patients who achieved PSA response or PSA stabilization, which is significantly lower than that of patients treated with docetaxel (18.9%, Lee et al. GU ASCO 2009, p = 0.005). The magnitudes of PSA surge were as follows: 8%, 14%, 62%, 63% and 111% above the baseline level. All PSA surge were observed during the first 4 weeks. The duration of PSA surge was 4 weeks in 3 patients and 8 week in one patient. No PSA surge lasted more than initial 12 weeks. No patients with PSA surge showed clinical deterioration (performance status deterioration or aggravation of pain) when PSA levels were elevated before going below the baseline level. There was a tendency that PSA surge was more frequently observed in patients who received abiraterone (4/38, 10.5%) compared to enzalutamide (1/60, 1.7%, p = 0.07). In addition to initial PSA surges, mid-cycle temporary PSA increases alternating with PSA decrease (we coined it as PSA fluctuation) were observed in 6 patients. Neither PSA surge nor PSA fluctuation had prognostic impact on overall survival.

Conclusions: Compared to cytotoxic chemotherapy, PSA surge occurs only in minority of patients with CRPC treated with NAPi. It tends to occur more frequently when patients were treated with abiraterone. PSA surge resolves within 12 weeks after treatment initiation and did not accompany clinical deterioration. Physician and patients should be well aware of this phenomenon not to discontinue effective treatment inappropriately.

P063
Long term clinical outcomes and toxicity of salvage radiotherapy after radical prostatectomy for prostate cancer patients
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Introduction & Objectives: After radical prostatectomy, as primary treatment of prostate cancer, approximately 15–40% of men develop a biochemical relapse within 5 years and the standard treatment is salvage radiation therapy (SRT). However, appropriate selection of patients is required and clear information concerning acute and late toxicity remains scarce. In this retrospective single institutional series we report long term biochemical recurrence (BR), acute and late toxicity.

Material & Methods: Data of 245 patients treated with SRT because of BR after radical prostatectomy were retrospectively collected from patient records. Patients were treated in the period between 1998–2012 with SRT. Primary end points were biochemical recurrence free survival (BRFS), acute and late toxicity. Secondary end points were DMFS, DSS, OS. BR was defined as a successive rise in PSA level ≥0.2 ng/mL after SRT. Acute toxicity was collected according to the RTOG criteria up to 90 days after completing SRT and late toxicity thereafter.

Results: Median age at start of SRT was 66 years (range 45–79 years). Patients received a median SRT dose of 72 Gy (range 68–78 Gy). Median follow-up after SRT was 47.7 months (range 3–150 months). Acute genitourinary (GU) toxicity and gastrointestinal (GI) toxicity grade ≥2 was 19.2% (n = 47) and 17.9% (n = 44), respectively. Late GU toxicity grade ≥2 was 27.7% (n = 68) with 2.4% (n = 6) grade 4 toxicity. Haematuria (gr. 2) and obstructive complaints (grade 3) were the most frequently reported late GU complaints. Late GI toxicity grade ≥2 was 20.8% (n = 51) with mainly rectal blood loss (grade 2). At start of SRT 69.4% (n = 170) of patients was continent for urine. Incontinence complaints occurred in 7.8% (n = 19) and 26.1% (n = 64) of patients in the acute and late phase, respectively. During the follow up only 50.6% (n = 124) of patients remains continent for urine. The 5 and 8 years BRFS rate after SRT was 58.1% (n = 136) and 56% (n = 131), respectively. In univariate logistic regression analysis for biochemical response, including: Initial PSA, PSA before SRT, T stadium, Gleason score, seminal vesicle invasion and positive margins, only Gleason >7 and seminal vesicle invasion predicted a higher BR rate. The 5 and 8 years DMFS was 90.2% (n = 211) and 89.7% (n = 210), respectively. The 5 years DSS and OS was 99.1% and 95.7%, respectively. The 8 years DSS and OS was 98.3% and 93.2%, respectively. Hormonal therapy was given in 22.7% (n = 53) of patients presented with BR after SRT. In 12/53 and 21/53 patients lymph node and distant metastasis was reported, respectively.

Conclusions: BRFS was conform the best series from the literature. High Gleason scores and seminal vesicle invasion was predictive for BR. The SRT treatment is well tolerated, however with a considerable percentage of patients with acute and late toxicity. Especially the decrease in urine continence should be discussed when advising patients.

P064
Smartphone cancer app usage among EAU Delegates – A survey

Introduction & Objectives: Smartphones currently have various uses in Medicine and the availability of mobile medical applications (apps) is increasing every day, with close to 100.000 medical apps available for Android (Google) and iOS (Apple). These new tools are changing the daily practice of Medicine, and Urology is no exception. The aim of our study was to get an insight in the usage of cancer-related medical apps by delegates of the EAU Congress.

Material & Methods: During the EAU Congress, delegates were given a pamphlet with a link to an online survey (Figure 1). The questionnaire evaluated the sociodemographic characteristics of the respondents and also their usage of smartphones and medical apps. Analyses were performed using Stata v.11.1 (Stata Corp., College Station, TX, USA).

Results: We distributed 400 pamphlets and received 111 filled out questionnaires. Respondents worked in 29 different countries, one-eighth in Italy. The average age was 44 years old (range from 27 to 62) and most were men (91%). More than half were Senior Urologists and half worked in Public Hospitals. Even though some had devices from multiple platforms, the majority used iOS (Apple) devices (84%). Almost every delegate used medical apps (97%), and 64% of them used it at least once a week, mainly during their clinical practice to look up medical information (77%). Ninety-one percent had apps about renal cancer, 82% had prostate cancer-related apps and 32% had apps about all urological cancers. Half of respondents only downloaded free apps (47%) and a third considered cost an important decision factor (37%). However, one third had spent between 10 and 50 euros on medical apps. The availability of the app in their native language and the endorsement by renowned experts were also considered pertinent (42% and 33%, respectively).

Only a small part of attendants used surgery related apps (22%).

Conclusions: To our knowledge, this is the first study that evaluates the mobile medical app usage of the EAU delegates. In our survey, the most popular apps were free and meant to be used during clinical practice.
The fact that the majority of the delegates had cancer related apps could be related to the increasing incidence of this disease. However, there were few surgery-related apps, which could represent an opportunity for future developments. With the anticipated improvement in software and hardware, a rapid growth of mobile medical technologies is expected. Therefore, the authors look forward to an increase in the quantity and quality of available urology cancer apps and believe that this could be an opportunity to improve care.

**Introduction & Objectives:** Efficacy of the PHI (Enzyme Immunoassay) for prostate cancer or suspected prostate cancer patients

J. Mo, National Evidence-based Healthcare Collaborating Agency, Seoul, South Korea

**Material & Methods:** Literature search was conducted using Ovid-Medline, Ovid-Embase and Cochrane Library. A total of 18 literatures were selected. Each of the stages from literature search to application of selection standards and extraction of data were carried out independently by 2 assessors under the deliberation by the Sub-committee. Tools of Scottish Intercollegiate Guidelines Network were used for assessment of the quality of literature, and levels of the basis and rankings of recommendation were selected accordingly to describe the results of the assessment.

**Results:** Diagnostic accuracy was assessed on the basis of a total of 18 literatures. Wide range of cut-off values at 24.9–48.5 was reported along with sensitivity in the range of 0.327–0.902, specificity in the range of 0.213–0.904 and AUC values in the range of 0.57–0.77, along with integrated sensitivity of 0.810 (95% ci 0.795–0.825) and integrated specificity of 0.449 (95% ci 0.432–0.467). As the result of separating the patients with PSA test results of higher than 4 ng/ml, integrated sensitivity of 0.506 (95% ci 0.442–0.571) and integrated specificity of 0.755 (95% ci 0.710–0.796) were reported. The prediction accuracy was assessed on the basis of a total of 8 literatures. The AUC value was in the range of 0.70–0.83 when PHI was added to the basic model. In 1 literature, it was reported that there is no significant difference in the AUC value upon addition of PHI (p = 0.136). Relevance with the results of prostate cancer biopsy was assessed on the basis of a total of 13 literatures. It is reported to be 34.7–56.5 for the prostate cancer patients with significant differences with the normal group. Although the integrated mean difference of PHI was reported to be significantly higher for the prostate cancer patients, the heterogeneity was high. There were 9 literatures that made prediction on the reduction rate of biopsy through statistical analysis model that it is possible to reduce unnecessary prostate biopsy at the rate in the range of 19.2–55.7 patients for each 100 patients by adding PHI. However, as the results of comparison with the actual results of biopsy in 3 literatures, it was reported that diagnosis of cancer was overlooked in 10–98 patients and 1 literature reported that there is no additional benefit to be obtained through this test.

**Conclusions:** Therefore, the Sub-committee made assessment that PHI [Enzyme IMMUNOASSAY] is a technology at the stage of needing further researches due to the insufficient research results that evidence that the technology can provide additional information for discrimination of the subject of prostate biopsy although there is no safety problem when applied to prostate cancer or suspected prostate cancer patients (Recommendation rating of C, Classification as technology in research stage i).
with negative studies or oligometastatic state, after signing an informed consent, became part of the study. WB-DWI-MRI and Cho-PET/CT explorations were made in less than 1 week between the two by studies and in the same equipments. All were read by experienced radiologist and nuclear medicine specialist, blinded from the other findings. If patients were candidates for SABR, they were assessed every 3 months with both tests. Analysis of correlation by statistical kappa (κ) assessed every 3 months with both tests. This was performed by a multidisciplinary team, based on the clinical and biological data for every patient, to determine the sensitivity and specificity of each test. After SABR we performed again correlation within.

**Results:** 29 patients were enrolled. Medians: Age 70 years, PSA of 3.17 ng/mL and testosterone 1.42 ng/mL, at time of the studies.

Location in the Cho-PET/CT: iliac/sacroiliac lymph-nodes 17.2%, 17.2% bone metastases, intraprostatic lesions 13.8% and 17.2% extrapelvic lymph-nodes. In WB-DWI-MRI, bone: Acetabulum 11.76%, sacroiliac/pubic 17.65%, sacrum 11.76%, spine 11.76% and lymph-node 5.88%.

Cho-PET/CT allowing detects lesions in 16 patients, who are not observable in the WB-DWI-MRI. There is agreement in 7 and only in 3 cases had WB-DW-MRI images not been observables in the Cho-PET/CT. The κ obtained was of 0.1 so that the correlation between tests is poor, the p-value is not significant, so the null hypothesis of κ = 0 is accepted. Besides the value of κ On the basis of the BVC, 10 patients presented metastases in bone and 14 in lymph nodes. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of WB-DWI-MRI were estimated to be 44.44%, 63.64%, 85.71% and 18.93%. For Cho-PET/CT, sensitivity, specificity, PPV and NPV were 95.74%, 60%, 91.84% and 75%. Both sensitivity and specificity were not comparable.

The test that best fits with the BVC was the Cho-PET/CT. Based on the findings of the Cho-PET/CT, 4 patients were candidates for SABR and complete response was observed after treatment in Cho-PET/CT assessment at 3 months.

**Conclusions:** There is no agreement between results of WB-DWI-MRI and Cho-PET/CT, latter allowing increased detection of no significant lesions on WB-DWI-MRI, especially in lymph-node metastases. If the lesions have been detected by Cho-PET/CT, with these initial data, we consider that have to assess the response to SABR with the same technique.

**P067**

**Urinary PCA3 score predicts good outcome in patients with advanced prostate cancer receiving androgen deprivation therapy**

A. De La Taille¹, L. Martinez-Piñeiro², P. Cabri³, A. Houchard⁴, J. Schalken⁵.

**Introduction & Objectives:** The Triptocare study (NCT01020448) showed that urinary PCA3 score was not a reliable marker of cancer stage in advanced prostate cancer and was not useful for assessing response 6 months after initiation of androgen deprivation therapy (ADT) with triptorelin 22.5 mg. An observational study assessed time to progression to castrate-resistant prostate cancer (CRPC) in patients included in the Triptocare study.

**Material & Methods:** This was an international, multicentre, non-interventional, longitudinal and prospective study involving all surviving and consenting patients in the Triptocare study. Information on CRPC status of all patients was collected for a maximum of 3 years from initiation of ADT. All treatment and assessment of patients was at the discretion of the investigator. The co-primary endpoints were rate of CRPC 3 years after ADT initiation and median time to CRPC, and an exploratory endpoint was association of variables at the initiation of the Triptocare study (age, PSA level, testosterone level, locally advanced or metastatic disease, Gleason score, TMPRSS2-ERG score, PCA3 score status) and PCA3 score status at the last visit in Triptocare with progression to CRPC.

**Results:** Of the 325 patients included in the Triptocare safety population, 180 were enrolled into this observational study: 102 patients received ADT continuously; 78 patients had intermittent ADT during the observational phase. Thirty-nine patients did not complete the 3 years of follow-up: 10 were lost to follow-up; 7 withdrew; 22 died. Baseline Gleason score, TNM staging and PCA3 score status of the 180 included patients resembled the baseline data for the Triptocare safety population. CRPC rates 3 years after starting ADT were 6/78 (7.7%) and 24/102 (23.5%) in those receiving intermittent ADT and those receiving continuous ADT, respectively. A multivariate analysis showed PCA3 score status at baseline was the only variable associated with a higher risk of progression to CRPC in patients receiving intermittent ADT – compared with a baseline PCA3 score ≥35, PCA3 score below the level of quantification (BLQ) had a hazard ratio (HR) of 20.04 (95% CI: 2.71–148.34). In patients receiving continuous ADT, PCA3 score BLQ had a HR = 9.44 (95% CI: 2.39–37.27). Baseline metastatic disease was associated with progression to CRPC in the continuous ADT population: HR = 5.20 (95% CI: 1.68–16.06).

**Conclusions:** In men with locally advanced or metastatic prostate cancer, a PCA3 score ≥35 at the time of initiating ADT may predict a lower risk of developing CRPC in the following 3 years, with continuous or intermittent ADT. Patients with a greater risk of developing CRPC may be more likely to receive continuous ADT than intermittent ADT. Further studies on the potential predictive role of PCA3 scores in advanced prostate cancer are needed.
A phase III, multicenter, open-label, pharmacokinetic, efficacy and safety study of new sustained-release leuprolide acetate 22.5 mg depot formulation in prostate cancer patients

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Introduction & Objectives: A new sustained-release 3-month leuprolide acetate 22.5-mg depot formulation with a unique double control release system has been developed. This study investigated the efficacy, safety profile and pharmacokinetics of this new formulation for suppressing serum testosterone levels in patients with prostate cancer.

Material & Methods: This was a Phase III, open-label, multicenter clinical trial. Patients with prostate cancer (all stages) who, in the judgement of the investigators, could benefit from androgen deprivation therapy were enrolled in the study at 25 investigational sites within the United States. Patients received two quarterly intramuscular injections of leuprolide acetate 22.5-mg depot. Plasma testosterone levels were determined at different specific times through the study duration with three of them defined as key time points (Day 28, 84 and 168) to evaluate efficacy. Secondary efficacy endpoints included luteinizing hormone (LH), follicle-stimulating hormone (FSH), serum prostate-specific antigen (PSA) and safety assessments A pharmacokinetic (PK) study of the drug was also conducted.

Results: All 161 patients from the ITT population received at least one dose of study drug. The 163 patients enrolled in the study constituted the safety population. The proportion of successful patients over the total number of ITT patients was 98.1%, the proportion of RTT patients who showed castrate testosterone levels at all key time points (Day 28, 84 and 168). The pharmacodynamics (PD) for testosterone showed that the median time to reach castration level was 28.0 days and maintained very low plasma levels until the end of the study. The pharmacokinetic (PK) profile of leuprolide showed sustained release of leuprolide from the formulation through all study time period. This unique PK profile results from a novel double control sustained peptide release system. The combination of polymer and TEC, as a second lipidic barrier, modulates the initial surge ensuring constant liberation of leuprolide throughout the three month period.

As expected, following the first administration there was a transient rise in mean serum LH concentrations. From Day 28 until the end of the study, mean serum LH concentrations were BLQ. The mean serum FSH concentration followed an equivalent pattern. Following the first administration, the level of PSA was maintained until Day 14 after which PSA progressively decreased until BLQ was achieved.

A small number of patients, although successful in the study in terms of achieving castration, had a slight punctual increase in testosterone levels. None of these patients showed an LH or PSA increase associated and none experienced any clinical exacerbations. The mechanism of action of these testosterone transient escapes reflects a likely extra-hypothalamic-pituitary-gonadal axis etiology. Regarding safety endpoints, the results are in line with other leuprolide acetate 22.5 mg depot formulations already at the market.

Conclusions: The results of this open label phase III study demonstrate that a novel three month Leuprolide acetate 22.5 mg depot formulation with a unique double control release system is effective in achieving and maintaining testosterone concentration below castration levels in prostate cancer patients. In this study, Lutrate Depot 22.5 mg, demonstrated a good safety profile and was well tolerated by patients.
by 12 months ADT did not induce detrimental effects on bone health in terms of increased bone fracture risk. This was the first prospective study on BMD changes as a predictor of fracture during ADT in an Asian population.

**P071**

**Testosterone suppression with an innovative form of leuprorelin acetate as solid biodegradable implant in patients with advanced prostate cancer. Results from four trials and comparison with traditional leuprorelin acetate microcapsules formulation**

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**Introduction & Objectives:** A new pharmaceutical ready-to-use form of leuprorelin acetate as solid, fully biodegradable implant (LEU) has been developed for the treatment of advanced prostate cancer (PCa) once every 3 months. In comparator-controlled trials and comparison with traditional leuprorelin acetate microcapsules formulation

**Material & Methods:** Four studies were conducted in patients with histologically confirmed diagnosis of PCa (T3–4N0M0, T1–4N1M0, T1–4N0–1M1) and T level ≥2.3 ng/mL (morning value): (1) a randomised, controlled single-dose study comparing LEU with TRE, (2) a single-arm single-dose study of LEU, (3,4) two long-term studies with LEU administered twice, either 12 or 16 weeks apart. The primary endpoints were the proportion of patients with T suppression ≤50 ng/dL after LEU or TRE administration.

**Results:** Following application of a single-dose of two different formulations of leuprorelin acetate, there were no relevant differences in T levels between treatment groups at weeks 4, 8 and 12 (Table).

**Table: T levels in single-dose studies**

<table>
<thead>
<tr>
<th>T level (ng/dL)</th>
<th>Leuprorelin implant</th>
<th>Leuprorelin microcapsules</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 4</td>
<td>Week 8</td>
</tr>
<tr>
<td>N</td>
<td>60</td>
<td>61</td>
</tr>
<tr>
<td>Median</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>95% CI</td>
<td>20–40</td>
<td>20–40</td>
</tr>
</tbody>
</table>

The median T levels remained stable throughout the single-dose studies, approximating 30 ng/dL at weeks 4, 8 and 12.

In the long-term 24-week study after repeated dose, all median values of T were below 20 ng/dL: starting at week 4 (13.6 ng/dL) until week 24 (9.1 ng/dL). The mean T value at week 24 was 13.43 ng/dL.

In the 32-week study with repeated administrations, the maximum T value was 17.1 ng/dL and all mean and median values were below 20 ng/dL.

**Conclusions:** Testosterone values during and at study completion were comparable between LEU and TRE after single administration with 12 weeks follow-up time. In both long-term studies with repeated administrations, LEU 3-month rapidly achieved steady serum levels of T below 20 ng/dL (as currently recommended by the EAU Guidelines) with excellent testosterone suppression comparable to orchiectomy, already achieved at week 4 and maintained for up to 32 weeks.

**P072**

**Clinical characteristics and treatment patterns of patients with prostate cancer (PCa) receiving leuprorelin acetate implant: First analysis from the non-interventional German cohort study (LEAN)**

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**Introduction & Objectives:** Interactions between hormonal therapy of PCa, comorbidities and lifestyle are complex but highly relevant for the course of the disease. The LEAN study aims at the analysis of the associations between anamnestic factors, PSA and testosterone dynamics and metabolic parameters. Furthermore, therapy patterns in urological practice were studied.

**Material & Methods:** Metabolic data (blood glucose, HbA1c, triglycerides, total, LDL and HDL cholesterol; albumin in urine), blood pressure, PSA, testosterone, diet and physical activity were assessed approximately every 3 months in 900 PCa patients in 190 centres, starting treatment with a leuprorelin implant (Leuprone® HEXAL®). The study accrual started in January 2014; patients are followed for 1 year. We report the first planned interim analysis describing baseline characteristics and treatment patterns of 657 patients. Data are presented as mean ± standard deviations.

**Results:** The median patient age was 75 years (range 51–92). Primary diagnosis of PCa was made 26±47 months before inclusion in the study with initial PSA levels of 73±280 [median: 15] ng/mL and serum testosterone of 5.6±19.6 [median: 3.8] ng/mL. Tumour stage at inclusion was T1 in 23%, T2 in 25%, T3/4 in 37%, and Tx in 10% (T0; 2%; missing: 3%); cN0 was reported for 39%, N1 for 17%, N2/3 for 2%, and Nx for 37% (missing: 5%); 52% were M0, 43% of the patients had metastatic disease (missing: 5%). More than 50% of patients suffered from comorbid cardiovascular diseases, >25% from disorders of glucose or lipid metabolism. Three, 6, 9 and 12 months after the start of leuprorelin therapy, median PSA values decreased to 0.6, 0.2, 0.2 and 0.2 ng/mL, respectively. At the same time points, median testosterone levels were 0.15, 0.13, 0.14 and 0.13 ng/mL. Of 190 participating centres, 118 provided information on standard treatment patterns. A median of 250 PCa patients were treated per centre. Seventy-six percent of patients with primary metastatic PCa received GnRH monotherapy, 54% maximum androgen blockade and 22% used monotherapy with an anti-androgen (multiple answers possible). Intermittent androgen deprivation was used in 17±22% of patients. PSA and testosterone are determined quarterly in 84% and 33% of patients, respectively; testosterone is determined without fixed schedule in an additional 35% of patients. Adherence to the guidelines of the German Society for Urology (DGU) and the EAU was reported in 97% and 72%.

**Conclusions:** Centres’ self-assessments promise a high adherence of PCa therapy to guidelines. Patients treated in clinical routine tend to be older and have an increased comorbidity. Further analyses will focus on interactions between anamnestic factors and the course of disease.
P073
Phase 1b study of ARN-509 with abiraterone acetate and prednisone in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC)

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Introduction & Objectives: ARN-509 and abiraterone acetate (AA) target the androgen receptor (AR) axis via different mechanisms and may have complementary activity in mCRPC. ARN-509, a potent and selective AR antagonist, inhibits AR nuclear translocation and DNA binding without significant AR agonist properties (Clegg, Cancer Res. 2012). AA is a prodrug of abiraterone, a CYP17 specific inhibitor that blocks androgen synthesis. No overlapping toxicities are expected for the combination. This phase 1b study evaluates potential pharmacokinetic drug-drug interaction, antitumor activity, and safety of ARN-509 in combination with AA + prednisone (P) (NCT02123758).

Material & Methods: Pts with progressive mCRPC and Eastern Cooperative Oncology Group performance status ≤2 received AA (1000 mg/d) + P (5 mg BID) beginning on Cycle 1 Day 1 (C1D1) with the addition of ARN-509 (240 mg/d) on C1D8 in 28-day treatment cycles. Efficacy assessment was based on Response Evaluation Criteria in Solid Tumors and Prostate Cancer Working Group 2 criteria.

Results: 29 pts started treatment on study. Median age was 70 years (range 49–83) and median prostate-specific antigen (PSA) was 111.0 μg/L (range 41.2–259.7 μg/L). Bone, nodal, and visceral disease were present in 25 (86%), 16 (55%), and 7 (24%) pts, respectively. 13 (45%) pts were previously treated with docetaxel, 12 (41%) with AA, 10 (34%) with enzalutamide (ENZ). 15 pts were discontinued from the study (12 for disease progression, 2 for consent withdrawal, 1 for physician decision). The proportion of pts who had a confirmed PSA response ≥50% while receiving ARN-509 with AA+P was 38% (95% CI, 21–58%). Most common drug-related adverse events (AEs) were grade 1/2 and included fatigue (n=13 pts), dysgeusia (n=6 pts), and hypokalemia (n=6 pts). Grade 3/4 drug-related AEs were hypokalemia (n=2 pts), hyponatremia (n=1 pt), fatigue (n=1 pt), and increased alanine aminotransferase (n=1 pt), and were managed by drug interruption and supportive measures.

Conclusions: Interim data indicate that ARN-509 in combination with AA+P is well tolerated in pts with mCRPC. Results indicate that ARN-509 with AA+P shows antitumour activity in pts with mCRPC, including both AA+P- and ENZ-pretreated patients. Further study of the efficacy and safety of ARN-509 and AA+P for mCRPC is warranted.

P074
Bone oligometastatic prostate cancer patients: Could “radical” radiotherapy be a reasonable choice?

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Introduction & Objectives: to evaluate toxicity, clinical outcome and predictive response factors in patients (pts) with prostate cancer (PCa) oligometastatic (≤2) to the bone at diagnosis, simultaneously treated with curative radiotherapy (RT) to primary tumour/prostatic bed (PB) and bone metastases.

Material & Methods: From February 2009, 29 pts with oligometastatic PCa (OPC), 15 of whom previously treated with radical prostatectomy and pelvic lymphadenectomy, underwent RT at “radical” dose to bone metastases (median 2-Gy equivalent dose, EQD2, >40 Gy, for α/β=2.2), to the pelvic ± lomboaortic nodes (51.8 Gy), and to the PB (median EQD2 72.4 Gy) or the prostate (median EQD2 88 Gy) within the same RT course in association with androgen deprivation therapy (ADT). Biochemical relapse-free survival (bRFS), clinical failure-free survival (CFSS, freedom from any clinical failure) and freedom from distant progression (FFDP) were considered.

Results: After a median follow-up of 19 months, 2 pts died, 2 were lost to follow-up, 2 showed in-field and 7 out-of-field progression, 3 have ended ADT and are still free from any progression. Acute toxicity was very mild with no Grade ≥3 events, and only 2 serious late events, 1 G3 and 1 G4 late urinary toxicity, only in the hypofractionated postoperative cohort. With respect to bone irradiation, no Grade ≥1 toxicity were reported. The 2-year actuarial values of bRFS, CFSS, FFDP are 63%, 66% and 63%, respectively.

When considering the most significant clinical end-point, FFDP, the most predictive factors were: PSA at diagnosis (iPSA >24.2 ng/ml, most-informative cut-off, AUC 80%, p=0.001) (HR=5.4, p=0.01), 2 vs 1 metastasis (HR=4.1, p=0.02), and no previous prostatectomy (HR =3.6, p=0.06), while no role emerged for the site of metastases (pelvic or not). When stratifying pts by the presence of 0, 1, 2, 3 risk factor, the 2-year actuarial FFDP was 100%, 75%, 33% and 0% respectively (p=0.03, Figure 1).
**Conclusions:** Radical or adjuvant radiotherapy in OPC, including RT at "radical" dose to bone metastases, seems to be a promising approach, with limited toxicity and leading to good local and distant control in selected patients. Although the well evident limits of a small cohort with a limited follow-up, this series would suggest that the ideal candidate could be a previously operated patient, with a PSA ≤24.2 ng/ml and with only one bone metastasis.

**P075**

Image guided moderate hypofractionation in prostate cancer: Phase I–II study 5 year results

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**Introduction & Objectives:** To report 5-year clinical outcomes and late toxicity in prostate cancer patients (pts) treated with Image Guided Radiotherapy (IGRT) Moderate Hypofractionated Simultaneous integrated boost (SIB) by Tomotherapy in a Phase I–II study.

**Material & Methods:** 211 pts (78 low-risk [LR], 53 intermediate-risk [IR] and 80 high-risk [HiR]) were treated between 2005 and 2011. IR and HiR pts received 51.8 Gy on pelvic lymph-nodes (LN) and concomitant SIB to prostate up to 74.2 Gy in 28 fr; LR pts were treated to the prostate to 71.4 Gy in 28fr. Androgen deprivation (AD) was delivered to 33%, 43% and 88% of LR/IR/HiR pts for a median time of 6, 12 and 34 months respectively. The gastrointestinal (GI) and genitourinary (GU) late toxicities were recorded according to the RTOG scoring system. Biochemical relapse free (bRFS) survival (Phoenix definition), cancer-specific (CSS) and overall survival (OS) actuarial curves were assessed. Selected clinical/dosimetry variables were tested as potential predictors of GI /GU toxicity and of BCR/CCS/OS (Cox test).

**Results:** Median follow was 60 (4–98) months. The 5-year incidence of late toxicity was: GU ≥G2: 20.2%; GU ≥G3: 5.9%; GI ≥G2: 17%; GI ≥G3: 6.3%. The prevalence at the last control was: GU ≥G2: 7.1%, GU ≥G3: 1.9%; GI ≥G2: 5.2%, GI ≥G3: 1.9%. Best predictors of ≥G3 GU and GI late toxicity were GU acute toxicity ≥G2 (HR: 4.9) and previous surgery (HR: 3.4) respectively. The overall 5-year bRFS OS and CSS are presented in the table. Androgen Deprivation and class risk were not correlated with bRFS/OS/ CSS.

<table>
<thead>
<tr>
<th>NCCN</th>
<th>N</th>
<th>Sy bRFS</th>
<th>OS</th>
<th>CCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>78</td>
<td>94.6% (-2.6)</td>
<td>90.5% (-3.4)</td>
<td>98.7% (-1.3)</td>
</tr>
<tr>
<td>Inter</td>
<td>53</td>
<td>92.2% (-2.6)</td>
<td>87.4% (-4.9)</td>
<td>95.0% (-3.5)</td>
</tr>
<tr>
<td>High</td>
<td>80</td>
<td>91.1% (-4.0)</td>
<td>87.0% (-4.5)</td>
<td>94.3% (-3.9)</td>
</tr>
<tr>
<td>Total</td>
<td>211</td>
<td>93.7% (-1.9)</td>
<td>88.6% (-2.4)</td>
<td>97.5% (-1.3)</td>
</tr>
</tbody>
</table>

**Conclusions:** The combination of pelvic LN irradiation and high dose to the prostate (EQD2 = 88 Gy) delivered with daily image-guided, intensity-modulated, moderate hypofractionation resulted in an excellent 5-year outcome, even in IR/HiR patients. The 5-year toxicity profile was acceptable with G3 incidences around 6%. The drastically reduced prevalence at the last follow-up for both ≥G2 and ≥G3 toxicities shows that symptoms were recovered in most patients.

**P076**

Toxicity and efficacy of salvage tomotherapy Choline PET/CT guided in patients with prostate cancer lymph nodal recurrence

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**Introduction & Objectives:** To evaluate the results of toxicity and disease control, with a follow up of 36 months, in patients with prostate cancer (PCa) lymph nodal relapse (LNR) treated with salvage tomotherapy Choline PET/CT guided.

**Material & Methods:** From 01/2005 to 03/2013 81 patients with LNR, detected by Choline PET/CT, after surgery +/- adjuvant/salvage radiotherapy (RT) or radical RT, were treated with salvage tomotherapy. Seventy-two/81 patients were treated on pelvic lymph nodes and/or lombo-aortic lymph nodes up to TD = 51.8 Gy/28 fractions, with a simultaneous integrated boost (SIB) up to 65.5 Gy on GTV-PET. Nine patients, with overlapping fields of therapy with those of the previous radiotherapy, were treated without SIB up to TD = 50–65.5 Gy/25–30 fractions. In 36 patients not previously irradiated it was treated also the prostatic bed.

Late toxicity, overall survival (OS), local control (LRFS) and clinical relapse free survival (CRFS) were evaluated. In 58/81 patients systemic therapy (androgen blockade/Estramustin/Ketoconazol) was prescribed; 22 of them were already castration resistant.

**Results:** With a median follow up of 36 (9–116) months, the incidence of late GI and GU toxicity ≥G2 was 7.6% and 22.8%; G3 toxicity 1.3% and 10.1% and G4 0% and 1.3% (1 patient, respectively). The presence of lymphedema ≥G2 was recorded in 7.3% of patients (1 patient G4 which required reconstructive surgery). The 3-year OS was 80%, LRFS 89.8% and CRFS 61.8%.

**Conclusions:** Choline PET/CT guided salvage tomotherapy in prostate cancer lymph-nodal relapse shows good local control and survival results. Considering that in our experience the GU toxicity after adjuvant/salvage radiotherapy showed a strong correlation with the hypofractionation, confirmed also by this study, the protocol was modified by excluding the hypofractionation in all cases requiring prostate bed irradiation.

**P077**

Bipolar plasma vaporization versus monopolar TUR in prostate cancer related urinary retention – A medium term, prospective, randomized-controlled comparison

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**Introduction & Objectives:** A prospective, randomized-controlled clinical analysis was aimed to assess the efficiency and safety of the bipolar plasma vaporization (BPV) by comparison to standard monopolar transurethral resection (TUR) in prostate cancer (PCa) cases associating complete urinary retention. Also, the short and medium term outcomes concerning the capacity to restore and maintain spontaneous voiding were compared.

**Material & Methods:** A total of 130 patients diagnosed with PCa in the locally advanced (with no indication for radical prostatectomy) or metastatic stage and complete urinary retention requiring catheter indwelling were equally randomized in the 2 study arms (65 cases each). The 1 year assessment was completed by 57 patients in the BPV series and...
55 in the TUR group. The cases were evaluated at 1, 3, 6 and 12 months after the initial surgery using a follow-up protocol that included International Prostate Symptom Score (IPSS), quality of life score (QoL), maximum flow rate (Qmax) and post-voiding residual urinary volume (PVR) measurements.

Results: The BPV technique emphasized significantly reduced capsular perforation rate (4.6% versus 11.3%) and mean operation time (36.7 versus 45.2 minutes) when compared to classical TUR. Moreover, BPV patients benefitted from substantially lower mean hemoglobin level drop (0.8 versus 1.45 g/dl) and important perioperative hematuria (requiring active measures) rate (7.7% versus 13.8%). Also, a faster postoperative recovery was observed in the BPV series, in light of the significantly decreased mean catheterization period (1.9 versus 3.2 days) and hospital stay (2.4 versus 3.9 days). On the other hand, equivalent early re-intervention (1.5% versus 3.1%) and irritative symptoms’ (18.5% versus 15.4%) rates were found following the 2 therapeutic approaches. During the periodical check-ups, no significant differences were determined between the 2 study groups with regard to the mean IPSS and QoL scores, Qmax and PVR features. During the 1 year follow-up, a similar proportion of patients (87.7% versus 89.1%, respectively) maintained spontaneous voiding subsequent to the 2 treatment alternatives.

Conclusions: The plasma vaporization procedure was confirmed as a viable therapeutic modality in PCA cases associating complete urinary retention. By comparison to conventional resection, BPV displayed the advantages of improved surgical speed, reduced perioperative bleeding risks and shorter convalescence period. Equivalent urodynamic and symptom score medium term’ parameters were described secondary to BPV and TUR. Furthermore, following either of the 2 techniques, a similar and satisfactory capability of maintaining a stable spontaneous voiding was underlined.

P078
Variation in prescription rate of the first post-docetaxel treatment and overall survival among patients with metastatic castration-resistant prostate cancer (mCRPC) in the Castration-resistant Prostate cancer Registry (CAPRI): An observational study in the Netherlands
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Introduction & Objectives: New post-docetaxel treatment options, such as cabazitaxel, abiraterone, enzalutamide and radium-223, improve health outcomes in mCRPC patients. The objective of this study was to evaluate whether variation exists in the prescription rate of the first post-docetaxel treatment (regardless of specific therapies) and overall survival (OS) in mCRPC patients and to explore the role of structural hospital characteristics.

Material & Methods: CAPRI is an observational study in 20 hospitals in the Netherlands. Patients who have been diagnosed with mCRPC in the period 2010 to 2013 and received docetaxel before 1–1–2014 were selected from the registry. Structural hospital characteristics were assessed based on annual volume of mCRPC diagnoses, hospital type, participation in mCRPC trials, hospital region and referral time from diagnosis to first consultation of medical oncologist. The outcomes prescription rate and OS were adjusted for known prognostic factors: age, ECOG performance status, opioid analgesic use, disease site, PSA, alkaline phosphatase (ALP), hemoglobin and lactate dehydrogenase (LDH).

Results: We identified 653 patients treated with docetaxel. The median percentage of patients who received any post-docetaxel treatment was 61% and varied between hospitals from 35% to 87% (figure 1). The odds of receiving this treatment were significantly higher in semi-specialized (OR 1.875, p=0.026) or specialized hospitals (OR 1.692, p=0.026) as compared to general hospitals. However, this difference was not retained after case-mix correction. We observed no association between prescription rates and the other hospital characteristics. Median OS adjusted for case-mix was 17 months for patients who received any post-docetaxel treatment as compared to 9 months for patients who did not. The median OS per hospital was not significantly related to the first post-docetaxel prescription rate.

Figure 1. Funnel plot of percentage of patients who received any post-docetaxel treatment per hospital type (specialized, semi-special or general hospital) and median overall survival per hospital type in months.

Conclusions: This study shows that variation exists in prescribing the first post-docetaxel treatments between Dutch hospitals, which cannot be explained by structural hospital characteristics after adjustment for case-mix. mCRPC patients treated with any post-docetaxel treatment had a significantly higher survival. However, variation in prescription rate of the first post-docetaxel treatment between Dutch hospitals does not seem to affect the median OS.

P079
Prospective objective response evaluation after prednisone-dexamethasone switch in castration resistant prostate cancer (CRPC) patients treated with abiraterone
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Introduction & Objectives: Abiraterone acetate (AA) has achieved a significant improvement in overall survival in CRPC. AA shows a favourable tolerance profile, administered associated with prednisone to decrease adverse events derived from the CYP171A suppression.

In the phase I/II of AA without steroids, dexamethasone 0.5 mg/day was added after biochemical progression reaching a 25% of PSA decline. Lorente et al (BJC, 2014) found in a 30 patients cohort treated with AA post-docetaxel that the switch leaded to durable biochemical responses in 40% of cases. Our hypothesis is that the dexamethasone-prednisone switch in patients with biochemical progression to AA + prednisone
would achieve objective secondary responses in the pre and post-docetaxel setting.

**Material & Methods:** The change of prednisone 5 mg/12h by dexamethasone 0.5 mg/24h has been tested prospectively in clinically stable CRPC patients with biochemical progression (PSA >25% nadir, confirmed in a second determination) and/or limited radiological progression (The biochemical response was monitored with PSA each 4 weeks. PSA progression was evaluated according to PSAWG2 criteria. Radiological response was re-evaluated after 12–16 weeks using bone scintigraphy and CT-scan according RECIST y PSAWG2 criteria. Survival outcomes were calculated using Kaplan–Meier method.

**Results:** 22 patients were included (10 pre-docetaxel, 12 post-docetaxel). Clinical characteristics of patients: Median age 72 years (63–88); ECOG 0 (9.1%), 1 (72.7%), 2 (18.2%); presence of visceral 22.7%, bone 86.4% and lymph node metastasis 54.5%; Gleason 6 (9.1%), 7 (22.7%), 8 (31.8%), 9 (31.8%), 10 (4.5%); medium PSA level before starting AA + prednisone of 75 ng/mL, medium PSA level before starting AA + dexamethasone of 105 ng/mL. Response evaluation: 79% of patients treated with the switch presented biochemical response, 30% of those achieved a PSA decrease >30%. Two radiological responses were observed. Biochemical progression-free survival reached with AA + prednisone was 4.9 months (95% CI 2.7–6.9) and after switch 4.3 months (95% CI 1.8–6.7).

**Conclusions:** In selected patients with clinical stability and limited disease progression, the prednisone-dexamethasone switch as co-adjutant of abiraterone acetate could be an acceptable therapeutic option.

Update results will be presented in the EMUC15 congress.

**P080**

**The PRESIDE Trial: A randomised, double-blind, placebo-controlled phase III efficacy and safety study of continued enzalutamide plus docetaxel after disease progression on enzalutamide alone in patients with metastatic castration-resistant prostate cancer**

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**Introduction & Objectives:** Enzalutamide is an oral androgen receptor inhibitor approved in the US for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) (US PI, 2014) and in the EU for the treatment of asymptomatic/mildly symptomatic men with mCRPC after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated, or those whose disease has progressed on or after docetaxel therapy (EU SmPC, 2014). The PRESIDE study (NCT02288247) will evaluate the efficacy and safety of continued enzalutamide treatment versus placebo when starting docetaxel plus prednisolone after disease progression on first-line enzalutamide in patients with chemotherapy-naïve mCRPC.

**Material & Methods:** PRESIDE will consist of an open-label treatment period with enzalutamide (period 1), followed by a randomised double-blind treatment with continued enzalutamide or placebo in addition to docetaxel plus prednisolone (period 2). Eligibility criteria include confirmed prostate adenocarcinoma, metastatic disease, prostate-specific antigen (PSA) progression on androgen deprivation or surgical castration, Eastern Cooperative Oncology Group performance status 0–1, testosterone ≤50 ng/dL, and minimally symptomatic patients (Brief Pain Inventory Short Form, question 3.2 every 3 weeks plus prednisolone 10 mg/day). The primary end point is radiographic progression-free survival. Secondary end points include PSA and pain progression, PSA and radiographic response, opiate use for cancer-related pain, skeletal related events and quality of life. Planned enrolment is 650 patients in 90 sites across Europe for period 1, with >137 patients in each randomised arm for period 2. Recruitment commenced in December 2014.

**Results:** As of 22 June 2015, 235 patients had been assigned treatment in Period 1 of the study. Study sites are in Austria, Belgium, Norway, Poland, Czech Republic, France, Germany, Greece, Italy, Spain, Sweden, UK, Turkey, and Russia.

**Conclusions:** The PRESIDE trial will assess if continued treatment with enzalutamide in combination with docetaxel chemotherapy offers clinical benefit over docetaxel chemotherapy alone.

**P081**

**Ketoconazole in patients with castration-resistant prostate cancer (CRPC): Efficacy, safety profile and risk factors for disease progression**

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**Introduction & Objectives:** Ketoconazole is an antifungal with adrenal and testicular antiandrogen action. It has anti-tumour activity by interfering with different cytochromes including C1720 – like the new hormonal therapies. Its use was generated controversy because the European Medicines Agency recommended the suspension of oral ketoconazole following a review of data showing higher liver toxicity with this medicine. We present our series of patients with CRPC treated with ketoconazole from the past four years to its oral suspension.

**Material & Methods:** Retrospective analysis of 46 patients with CRPC treated with ketoconazole. We analysed clinical data, prostate-specific antigen (PSA) response, progression-free survival (PFS) and toxicity profile. The prognostic value of different variables for PFS was assessed by Cox regression analysis. All statistical calculations were computed using SPSS 22.0. A level of significance of \( p < 0.05 \) was defined as a statistically significant.

**Results:** 46 patients (37 metastatic) with CRPC were treated with ketoconazole between 2010 and 2014 during a median follow-up of 12.4 months (7.2 to 25.3). PSA response was 26.7% (19.4% metastatic vs 55.6% non-metastatic) with PSA stabilization in 20% (17.9% metastatic vs 33.3% non-metastatic). 17 patients (37%) has been remained free of progression after a median follow-up of 24.3 months (12.2–32 months). The median progression-free survival was 8 months (3.3–12.69 months), being 6 months (2.6–9.4 months) in the subgroup of metastatic. There is a 17.39% of liver toxicity (8 patients) that required treatment discontinuation in 87.5% of cases. In the univariate analysis: the presence of metastases at baseline, a prior response to an antiandrogen of 20 ng/mL were associated with progression disease significantly. In the Multivariate analysis, ECOG >1 (HR 3.7, \( p = 0.034 \)), a prior response to an antiandrogen of 20 ng/mL (HR 3.5, \( p = 0.01 \)) were associated with a shorter PFS duration.

**Conclusions:** In our study, ketoconazole is a moderate activity agent with acceptable safety profile for patients with CRPC. In very selected cases of metastatic CRPC might be an alternative therapeutic option. Regarding non-metastatic CRPC, ketoconazole still retains its place (with tight control of toxicity) until the results of the new clinical trials.
P082
Usefulness of predictive nomograms in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC) treated with ketoconazole

Introduction & Objectives: Ketoconazole may be a cost-effective option in patients with CRPC but modest efficacy, toxicity and the emergence of new antiandrogens make necessary to identify which patients will benefit from it. Keizman (2012) and Lin WG (2012) established two nomograms for patients with mCRPC treated with ketoconazole that classified them into three risk groups according to their median progression-free survival (PFS) estimated. In the present study we evaluate their usefulness in our cohort of patients.

Material & Methods: Retrospective study of 37 patients with mCRPC treated with ketoconazole from 2010 to 2014. Patients were classified in a risk group according to the two different nomograms. We evaluate PSA response and PFS. All statistical calculations were computed using SPSS 22.0. A level of significance of p < 0.05 was defined as a statistically significant.

Results: Most patients were stratified as favourable risk group according to the Keizman score and as intermediate risk group according to Lin (Table 1). All PSA responses were observed in the favourable and intermediate risk groups in the first case, while 17% of PSA responses were observed in the poor risk group of Lin. The area under the curve for PSA response was 61% vs 59%, respectively. The Keizman favourable risk group gives a Positive Predictive Value (PPV) of 32% and a Negative Predictive Value (NPV) of 86% for PSA response, and PPV of 12% and NPV of 64% for the same group in the Lin classification. The median PFS times were 10, 7 and 2 months in favorable, intermediate and poor risk group using Keizman nomogram (similar to the reported – 14, 7 and 3 months). When we used Lin classification the PFS times were 11, 36 and 2 months (instead of 36, 3 and 1.4 months).

Conclusions: In our patients nomogram published by Keizman et al. predicted more accurately the PSA response to ketoconazole and PFS than Lin nomogram did. It was uncommon a PSA response in patients who were not classified as low risk group according this nomogram (NPV 86%), so they might be the most benefited group from the treatment. The results with the nomogram of Lin WG et al. were more variable, and explained worse our results, may be it is due to the different ethnic origin.

Reference(s)

P083
Cabazitaxel re-challenge demonstrates significant clinical efficacy with minimal toxicity in patients with mCRPC who have previously received chemotherapy with docetaxel and cabazitaxel
C. Barker, S. Pan, R. Peck, A. Birtle. Royal Preston Hospital, Dept. of Oncology, Preston, United Kingdom

Introduction & Objectives: Prostate cancer is the most common malignancy in men, with over 40,000 cases diagnosed in the UK annually [1]. Many of these patients have locally advanced or metastatic disease at presentation. Docetaxel is recommended as first-line chemotherapy in patients with metastatic castrate-resistant prostate cancer (mCRPC). Further treatment options, and optimum sequences of regimes, for patients whose disease progresses post docetaxel is undefined. Cabazitaxel improves survival in patients with prostate cancer who have previously received docetaxel treatment [2]. We present the first case series of cabazitaxel re-challenge in patients with mCRPC.

Material & Methods: 7 patients who had been previously treated with cabazitaxel with good response received cabazitaxel re-challenge at standard dose (25 mg/m2). Patients were aged 55–76 years of age and received a median of 3 cycles (range: 1–10, with 3 patients receiving ongoing treatment). Maintenance of planned dose intensity was 100%. All patients received primary prophylaxis against neutropenic sepsis with GCSF. All patients had previous clinical response to cabazitaxel based subjectively on improvement in symptoms from mCRPC and/or biochemical response with decrease in prostate-specific antigen (PSA) or alkaline phosphatase (ALP). Time from previous cabazitaxel treatment ranged from 5 months to 2 years 8 months (mean: 3 years 8 months, median: 2 years 7 months).

Results: 5/7 patients had symptomatic benefit based on a decrease in analgesia requirements or assessment of performance status. Mean PSA reduction was 19,487ng/ml, median 126ng/ml (range: decrease of 97,118 to increase of 30ng/ml). The mean reduction in ALP value was 108.4IU/l, median 17IU/l (range: Decrease of 442 to increase of 68IU/l). The neutrophil lymphocyte ratio (NLR) value showed a mean increase of 3.32, median 0.6 (range: decrease of 2.5 to increase of 16.4). Results do not include 2 patients who have received the first re-challenge cycle of cabazitaxel only. All data will be mature at time of presentation.

2/7 patients discontinued treatment due to orthopaedic intervention and patient choice to stop all treatment for mCRPC. The main toxicity was grade 1 fatigue seen in 3/7 patients. There were no episodes of diarrhea, neutropenic sepsis, neuropathy or treatment related deaths.

Conclusions: In selected patients with mCRPC re-challenge treatment with cabazitaxel chemotherapy demonstrates clinical and/or biochemical response. No additional toxicity is seen compared with first line treatment and response rates in this limited series are concordant with those seen in first line therapy. The majority of patients had a significant symptomatic response; with reduction in pain and analgesia requirement. PSA and ALP are often discordant with observed symptomatic benefit.

Reference(s)
However, selected clinical trial populations may not be representative for the real world population. The objective is to compare docetaxel treatment within clinical trials and outside clinical trials (standard care) in Castration-resistant Prostate cancer Registry (CAPRI): An observational study in the Netherlands.

Table 1. Baseline characteristics for patients treated with docetaxel in standard care versus docetaxel in trial

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Docetaxel in standard care (n=615)</th>
<th>Docetaxel in trial (n=48)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>71 (65–76)</td>
<td>67 (61–74)</td>
<td>0.017</td>
</tr>
<tr>
<td>≥75 years (%)</td>
<td>32</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Gleason score (%)</td>
<td></td>
<td></td>
<td>0.134</td>
</tr>
<tr>
<td>≤7</td>
<td>35</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>8–10</td>
<td>54</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>11</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Period on ADT (months)</td>
<td>19 (11–33)</td>
<td>25 (15–48)</td>
<td>0.009</td>
</tr>
<tr>
<td>Missing (%)</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>ALP (U/L)</td>
<td>174 (99–406)</td>
<td>191 (122–367)</td>
<td>0.595</td>
</tr>
<tr>
<td>Missing (%)</td>
<td>19</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>LDH ≥ULN (250 U/L) (%)</td>
<td>No</td>
<td>39</td>
<td>0.305</td>
</tr>
<tr>
<td>Missing (%)</td>
<td>38</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>PSA (ug/L)</td>
<td>146 (57–360)</td>
<td>137 (72–261)</td>
<td>0.666</td>
</tr>
<tr>
<td>Missing (%)</td>
<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin (mmol/L)</td>
<td>7.6 (6.8–8.3)</td>
<td>8.1 (7.3–8.8)</td>
<td>0.005</td>
</tr>
<tr>
<td>Missing (%)</td>
<td>13</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>ECOG performance (%)</td>
<td>0</td>
<td>19</td>
<td>0.098</td>
</tr>
<tr>
<td>1</td>
<td>42</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>&gt;1</td>
<td>10</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>29</td>
<td>21</td>
<td></td>
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<tr>
<td>Disease site (%)</td>
<td>Lymph node only</td>
<td>3</td>
<td>0.173</td>
</tr>
<tr>
<td>Bone/Bone and lymph node</td>
<td>34</td>
<td>64</td>
<td></td>
</tr>
<tr>
<td>Visceral</td>
<td>14</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>49</td>
<td>21</td>
<td></td>
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<tr>
<td>Opioid use (%)</td>
<td>No</td>
<td>42</td>
<td>0.238</td>
</tr>
<tr>
<td>Yes</td>
<td>21</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>36</td>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

Median OS for trial patients was 23.6 months, compared to 16.9 months for standard care [hazard ratio (HR) 0.71, 95% confidence interval (CI) 0.48–1.04; p = 0.073]. After imputation, significant prognostic variables (p < 0.05) for survival were hemoglobin, LDH, opioid use, ECOG performance status and period on ADT. The HR for trial patients versus standard care in multivariate analysis was 1.11 (95% CI 0.74–1.68; p = 0.605).

**Conclusions:** We observed a trend to longer OS for patients treated in docetaxel trials versus standard care, which can be explained by baseline differences (hemoglobin, LDH, opioid use, ECOG performance status and period on ADT) and the number of docetaxel cycles given. The differences between the trial population and real world population warrant caution in the extrapolation of clinical trial results and outcome comparisons with real world observational studies.

**P085**

**The sequencing conundrum in metastatic Castrate-Resistant Prostate Cancer (mCRPC): Is this a missing key to unlocking the optimal sequence?**

**S. Pan, V. Kumar, N. Charnley, O. Parikh, A. Birtle. Rosemere Cancer Centre, Dept. of Oncology, Preston, United Kingdom**

**Introduction & Objectives:** The introduction of new life-prolonging treatments including docetaxel (D), cabazitaxel (C), abiraterone (A) and enzalutamide (E) have revolutionised the outcomes of patients with mCRPC. Treatment sequences remain variable dependent on physicians’ choices. The aim of this study is to evaluate outcomes in patients receiving cabazitaxel and its potential relevance on therapeutic sequencing.

**Material & Methods:** A retrospective study of mCRPC patients treated with cabazitaxel after progression during or following docetaxel at one centre in England. Data on thirty three patients relating to patients’ characteristics, treatments and clinical outcomes were collected from the medical records and anonymised for analysis.

**Results:** Thirty three patients analysed received a median (range) of 3 (2–4) different life-prolonging therapies. The median (interquartile range, IQR) age of patients commencing on cabazitaxel was 71.1 (67.4–75.1) years. Cabazitaxel was second line therapy after docetaxel in 22/33 (67%) patients. Median (IQR) time from mCRPC diagnosis to start of cabazitaxel was 1.5 (1.0–2.0) years.

The tabulated data describes the number of treatment used with the following sequences: 7 patients received 2 therapies (DC); 22 patients received 3 therapies (DAC: n = 7, DCA: n = 15); 4 patients received 4 therapies (DCAE: n = 1, DACE: n = 1, DCEA: n = 1); Overall survival was longer, with a 14 months addition in patients receiving second-line cabazitaxel compared to third-line following docetaxel and abiraterone.

**Conclusions:** Based on this one centre real-life practice sequencing data, there is evidence to suggest that cabazitaxel has optimal benefit on overall survival when used second line following docetaxel. This data is promising and may be the beginning to unlocking the sequencing conundrum. A multicentre study is being carried out to validate this data further.
P086
An audit and indirect comparison of the use of Cabazitaxel (CBZ) for the treatment of metastatic Castrate Resistant Prostate Cancer (mCRPC) progressing after docetaxel compared to previous experience with ECaRoF (epirubicin, carboplatin and 5-fluorouracil)

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Introduction & Objectives: Cabazitaxel (CBZ) has been shown to prolong survival in patients with mCRPC progressing after docetaxel. Before the availability of newer treatment options in the past 5 years, ECaRoF was used at University College London Hospital for this group of patients. The objective of the study was to determine the efficacy and toxicity of CBZ in routine clinical practice compared to ECaRoF.

Material & Methods: We conducted a single centre, retrospective evaluation of CBZ in comparison with ECaRoF. Survival was estimated using the methods of Kaplan–Meier and Cox proportional hazards. Toxicities and response rates were compared using Chi-squared and Fisher’s Exact test respectively.

Results: Twenty-three patients with mCRPC, who had previously received docetaxel, were treated with CBZ from 2013. Most patients in this group had also had one or two lines of secondary hormones before CBZ. This was in contrast to 35 patients treated with ECaRoF between 2007 to 2010; all of whom received ECaRoF as second line mCRPC treatment. The partial biochemical response rates (defined as at least 30% decrease in PSA from baseline at end treatment) were 34.7% and 37.1% in the CBZ and ECaRoF group, respectively. Previous response to docetaxel did not predict response to CBZ or ECaRoF. Median progression-free survival (PFS) was 2.7 months (95% CI: 2.0–4.9) for CBZ vs. 5.3 months (95% CI: 2.6–8.0) for ECaRoF. Median overall survival (OS) was 9.3 months (95% CI: 6.1–17.6) for CBZ vs. 13.1 months (95% CI: 7.6–27.2) for ECaRoF. There was a significant difference in PFS in the ECaRoF group (HR = 0.42; 95% CI = 0.24–0.75; p = 0.004), and a non-significant trend towards better OS (HR = 0.58; 95% CI = 0.29–1.14; p = 0.114). Treatment was generally well tolerated although there was 1 neutropenic death in each group. Grade 3/4 haematological toxicity was comparable in both groups and grade 3/4 non-haematological toxicities were more frequent in those treated with CBZ.

Conclusions: Patients receiving CBZ were more heavily pre-treated than ECaRoF patients limiting interpretation of the PFS comparison. However, both chemotheraphy regimens have activity in the post-docetaxel setting and efforts should be made to identify new predictive biomarkers.

P087
Toxicity assessment of pelvic volumetric modulated arc therapy for prostate for high-risk or locally advanced prostate cancer

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Introduction & Objectives: To report early toxicity of pelvic Volumetric Modulated Arc Therapy (VMAT) with hypofractionated simultaneous integrated boost (SIB) to the prostate for patients with high-risk or very high risk prostate cancer.

Material & Methods: Eighty-three consecutive patients, diagnosed with high risk or locally advanced prostate cancer, were treated definitively between June 2011 and May 2015 with SIB-VMAT. All of them also received androgen suppression. On the planning-CT CTV1, CTV2 and CTV3 were delineated: CTV1 included the prostate, CTV2 consisted on CTV1 plus seminal vesicles, CTV3 consisted on CTV2 plus pelvic nodes. CTVs were expanded to generate the planning target volumes (PTV). The VMAT plans were designed to deliver 67.5 Gy in 27 fractions (2.5 Gy/fraction) to the prostate, 59.4 Gy (2.2 Gy/fraction) while delivering simultaneously 48.6 Gy in 27 fractions (1.8 Gy/fraction) to the pelvic lymph nodes. In some patients with N1, dose was increased to 59.4 Gy at 2.2 Gy given simultaneously, and HDR brachytherapy 9 Gy/1 fraction was done in unfavorable dosimetry for integrated boost to the prostate. Toxicity was scored by CTCAEv4.0. Univariate and multivariate analysis were performed looking for correlations among patient characteristics, dose values and toxicity.

Results: Median age of those patients was 70 years old. Gleason score was 8 or higher in 70% of patients. The median follow-up period was 25 months (from 1 to 45 months). All patients received the prescribed external radiation dose in 27 fractions. Sixty-two patients received 67.5 Gy to the CTV1 plus margin at 2.5 Gy per fraction. Brachytherapy boost was performed in twenty-one patients delivering 9 Gy in one fraction over 59.4 Gy at 2.2 to the CTV2 plus margin. Four patients died during the follow-up period. One of them because a second tumour and the others three for prostate cancer progression. The most common acute event was urinary frequency/urgency (90%). Acute genito-urinary toxicity was scored as 1 in 70% of patients. Rectal acute toxicity grade 2 with mucosal discharge was present in 40% of patients. No late toxicity exceeding Grade 2 was seen in patients with follow-up greater than 6 months. Rectal toxicity grade 2 or less was 25%. Urinary toxicity grade 2 or less was 40%. Grade 2 acute or late bowel toxicity were seen in 8% and 4% respectively. Grade 2 acute or late bowel toxicity was not associated with bowel volume receiving V30, V40, V50 or V60 Gy. Acute or late bladder and rectal toxicity did not correlate with any of the dosimetric parameters examined.

Conclusions: Pelvic VMAT with SIB or sequential HDR brachytherapy to the prostate were well tolerated in this series with acceptable acute and subacute toxicity. SIB-VMAT combines pelvic radiotherapy and hypofractionation to the primary site and offers an accelerated approach to treating high-risk disease. Additional follow-up is necessary to fully define the long-term toxicity after hypofractionated, whole pelvic treatment combined with androgen suppression.
abiraterone) have been treated with Enzalutamide that was orally administered at 160 mg/day as continuous dosing. Patient characteristics included: median age 67 years (range 50–84), median baseline PSA 120 ng/ml (range 6–1200), median ECOG Performance Status: 1 (range 0–2), Gleason score ≥7. In addition 80% of pts had ≥2 metastatic sites. Pretreatment baseline and follow up data including measurement of serum Ca and PTH levels (6.5–36.8 pg/ml), alkaline phosphatase (ALP), PSA and Quality of Life (QoL) parameters were evaluated through all lines of therapy. Pts with bone metastasis received zoledronic acid or denosumab with Ca and vitamin D supplementation.

**Results:** In 18/20 pts with bone disease progression we recorded increased PTH levels and, correspondingly, decreased Ca levels after 1 month of Enzalutamide despite vit. D and Ca supplementation. PTH levels remained unchanged after 3 months. In 2/20 pts without bone disease progression PTH ranged normal. All pts reported PSA response ≥50%, with improved QoL and are still on treatment since Enzalutamide is well tolerated. We did not find PTH change in bone mCRPC pts treated with prior therapy.

**Conclusions:** Our study showed that increase in PTH levels and reduction in Ca levels and increase in PTH levels after 1 month of Enzalutamide treatment is associated with a dramatic reduction of PSA level. These data support a relationship between PTH and Ca changes in pts treated with Enzalutamide and, thus, their changes level may be adopted in clinical practice as surrogate to reflect the drug activity. No studies have evaluated the variations in serum PTH levels following Enzalutamide treatment and whether these early changes relate to the clinical outcome.

**P146**

Prospective observational assessment of the effectiveness of enzalutamide treatment in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC) in a real-world clinical practice setting: The ongoing PREMISE study

M. De Santis1, M. Borre2, R.P. Davidson3, R.J. Snijder4, H. Payne5.

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**Introduction & Objectives:** Enzalutamide (ENZA) is an androgen receptor signalling inhibitor approved in Europe for the treatment of asymptomatic/mildly symptomatic men with mCRPC after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated, or those whose disease has progressed on or after docetaxel therapy. While phase 3 ENZA studies provide efficacy/safety data obtained under controlled conditions, limited data are available on clinically relevant end points in a real-world clinical setting. Here, we describe the ongoing PREMISE study, which will capture data on effectiveness, health-related quality of life (HRQoL), safety and characteristics of patients with mCRPC prescribed with enzalutamide (ENZA) in a clinical setting.

**Material & Methods:** PREMISE is a long-term observational study in men with mCRPC who have been prescribed ENZA as part of standard clinical practice and provided informed consent to participate. A total of 1930 patients with mCRPC are planned to be enrolled from 200 sites across Europe and South Africa. Data collection is expected to continue until 2018. Ethics approval will be obtained from relevant committees and the study conducted in accordance with the Declaration of Helsinki. Data will be collected at baseline, all routine clinical visits (approximately every 3 months) and at study completion or disease progression or death. Data will be sourced from Serious Adverse Event/Adverse Drug Reaction Worksheets, hospital medical records and patient-completed questionnaires. Data will only be reported descriptively.

**Results:** Data collection began in the second quarter of 2015. As of June 2015, 74 sites in Europe were confirmed as suitable for study inclusion.

**Conclusions:** PREMISE data will contribute to the existing ENZA evidence base and provide valuable information on the effectiveness and safety of ENZA in patients with mCRPC in a real-world clinical setting.

**P089**

Neutrophil-Lymphocyte Ratio (NLR) is a prognostic factor for survival but not a predictive factor for Abiraterone treatment response in Docetaxel naive and Docetaxel treated mCRPC patients


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**Introduction & Objectives:** Inflammation plays a significant role in development and progression of various solid tumours including prostate cancer. A high neutrophil-to-lymphocyte ratio (NLR) has been reported to be a poor prognostic indicator in several malignancies. We assessed the prognostic role of pretreatment NLR Ratio in metastatic castration-resistant prostate (mCRPC) patients treated with Abiraterone.

**Material & Methods:** Patients treated with Abiraterone 1g daily with Prednisolone 10 mg daily were identified from the chemotherapy prescribing system (Chemocare). 149 consecutive patients treated between Jan 2012 and May 2014 were identified. We calculated NLR using pre-treatment baseline bloods and assessed whether this affected their response to abiraterone and overall survival.

**Results:** All patients were performance status of 0 or 1. For the whole population median age was 75.1 years (Range 54.9–88.1); median PSA was 52.3 (Range 0.03–6884), and median NLR was 3.05 (Range 0.8–32.4). Median PFS was 6 months (Range 20 days to 31 months) and median survival has not been reached. Based on literature review, a NLR cut off of 4 was adopted. There were 99 patients with an NLR 4. Baseline characteristics in the NLR 4 were well matched in terms of median age (75.6yrs vs 73.8yrs) and median baseline PSA (49.8 vs 56.8). More patients pre-treated with Docetaxel chemotherapy had a high NLR of >4 (48% vs 31.3% p = 0.046).

More than half (50.7%) of patients achieved ≥50% decline in prostate-specific antigen (PSA). There was no significant difference in response in groups with high and low NLR (53.5% vs 44.9% p = 0.32). There was no difference in progression free survival between the groups (6 months) however there was a significant difference in overall survival (OS), with the better OS in the lower NLR group compared to the high NLR group (Not reached vs 17.1 months, p = 0.05).

On univariate analysis of baseline variables (age, PSA, haemoglobin and alk phos), only alkaline phosphatase level
correlated significantly with PFS and OS time (weak negative correlation, r = -0.25, p = 0.002 & r = -0.331, p = 0.02). Type of metastases was not predictive of survival in this cohort. When controlled for NLR, there were no differences in PFS, OS or PSA response in patients previously treated with Docetaxel pre-treated versus Docetaxel naïve patients.

**Conclusions:** NLR is an inexpensive, readily available prognostic factor and a high NLR predicts poorer overall survival. But NLR is not a predictive factor for treatment response to Abiraterone in both pre and post Docetaxel setting. Hence NLR is not a predictive factor for treatment response to Abiraterone in both pre and post Docetaxel setting. Hence NLR is not a predictive factor for treatment response to

P090

Impact of body mass index on clinico-pathological parameters and outcome in patients with metastatic prostate cancer

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**Introduction & Objectives:** This study evaluates the correlation between body mass index (BMI) and clinicopathological parameters of metastatic prostate cancer (MPC) and its impact on survival.

**Material & Methods:** The study includes all MPC patients who diagnosed and treated between from January 2011 to March 2015 in our center. Patients with BMI <25.0 kg/m² were categorized as level I and patients with BMI ≥25.0 kg/m² were categorized as level II. Demographic features and survival rates were evaluated by using the Kaplan–Meier method and Cox proportional hazards models.

**Results:** According to BMI level, 31 patients (43.7%) belonged to level I while the rest belonged to level II. The median follow-up duration for level II patients was insignificantly higher than level I patients, p = 0.5. In terms of age, metastasis, serum level of albumin, prostatic specific antigen, alkaline phosphatase and Gleason score, there was no significant difference between two levels, however, lactate dehydrogenase level was significantly higher in level II patients than level I, p = 0.000. The cumulative survival probability in 10th, 20th and 30th in level I vs level II was 86%, 78%, 68.5% vs 77%, 68%, 64% respectively. In the level I group, 7 patients died of PC, while in the level II group 11 patients died, thus showing a higher PC-specific death rate in level II group.

In univariate and multivariate analysis, poor prognosis was associated with increasing alkaline phosphatase (HR = 1.0005, 95% CI 1.0005–1.001, p = 0.03, HR = 1.001, 95% CI 1.0001–1.002, p = 0.03) respectively, while better prognosis was associated with no visceral metastasis (HR = 0.09, 95% CI 0.03–0.2, p = 0.000, HR = 0.04, 95% CI 0.008–0.2, p = 0.000) and increasing albumin level (HR = 0.17, 95% CI 0.09–0.34, p = 0.000, HR = 0.15, 95% CI 0.05–0.4, p = 0.000) respectively. In multivariate analysis only, patients belong to level I was associated better prognosis (HR = 0.17, 95% CI 0.04–0.7, p = 0.02).

**Conclusions:** BMI is dependent prognostic factor in patients with MPC.

P091

Prognostic significance of stromal but not tumour-associated FGF-2 expression in prostate cancer

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**Introduction & Objectives:** Deregulation of FGF-2 expression is a frequent event in prostate cancer. It has previously been suggested that FGF-2 is secreted by stroma as paracrine growth factor at early stage of tumour development whereas later stages are characterized by a primarily autocrine secretion that renders tumour cells independent from microenvironmental signaling cues.

**Material & Methods:** We used a tissue microarray consisting of 571 tumour cores from 165 prostate cancer patients to show that this notion needs to be revisited. An immunohistochemical protocol was used to assess FGF-2 expression in tumour and stroma cells. Tumour cells and stroma cells were examined and scored separately.

**Results:** FGF-2 was strongly expressed in tumour cells in 32.1% (53/165) patients and in stroma cells in 16.4% (27/165) patients. We surprisingly found that stromal FGF-2 expression was significantly correlated with poor BCR-free survival (p < 0.05) while tumour-associated FGF-2 expression did not predict survival. In addition, higher stromal FGF-2 expression was closely related with Gleason grade (p ≤0.005) and clinical stage (p < 0.005). FGF-2 expression levels were found to be related with metastasis in both tumour cells (p < 0.05) and stroma cells (p < 0.01).

**Conclusions:** Our results show that microenvironmental effects play a critical role in tumour progression and disease outcomes, moreover these results may be suggested that FGF-2 expression in stroma cells can be used as an independent prognostic factor for prostate cancer.

P092

Prognostic factors of biochemical and radiological progression in patients with positive lymph nodes after surgical treatment

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**Introduction & Objectives:** The aim of the study was to assess prognostic factors of biochemical and radiological disease progression (DP) in subgroup of lymph node (LN) positive prostate cancer (PC) pts.

**Material & Methods:** Retrospective analysis of 1577 PC pts undergone radical prostatectomy (RPE) and pelvic lymph node dissection (PLND) was done. LN metastases were verified in 246 (15.6%). Mean PSA level was 23.7±22.8 ng/ml; mean percentage of positive biopsy cores was 76.0±27.8%. Clinical stage was T1b–T2c in 125 (30.8%), T3a–T3b in 121 (49.2%),
Biopsy Gleason score ≤6 was in 61 (24.9%) pts; 7 (3+4) in 60 (24.4%); 7 (4+3) in 73 (29.6%) and 8–10 in 41 (16.6%); not assessed in 11 (4.5%) pts. Low risk PC was verified in 6 (2.4%) pts, intermediate risk in 48 (19.5%) pts and high risk in 192 (78.1%) pts. Standard PLND was done in 78 (31.7%) pts, extended in 168 (68.3%) pts. Mean number of LN removed was 23±10 (2–53). Biochemical recurrence (BR) was assessed as elevated in PSA >0.2 ng/ml on three consecutive measurements. Radiological assessment included bone scan and MRI or CT in some patients.

**Results:** Follow-up status was available in 186 (75.6%) pts. Mean follow up was 30.2 (2–53) months. Biochemical recurrence (BR) was assessed as ± extended in 168 (68.3%) pts. Mean number of LN removed was 19.2 (78.1%) pts. Standard PLND was done in 78 (31.7%) pts, 6 (2.4%) pts, intermediate risk in 48 (19.5%) pts and high risk in not assessed in 11 (4.5%) pts. Low risk PC was verified in 60 (24.4%); 7 (4+3) in 73 (29.6%) and 8–10 in 41 (16.6%);

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sensitivity: 52.4%). Kaplan–Meier plots stratified according to TV cut-off showed an early CF in patients who had TV > 7 ml (Log-rank $P<0.001$).

In model 1, only PSA (HR 1.013; 95%CI, 1.004–1.033, $P=0.03$) and GS ≥ 8 (HR 4.659; 95%CI, 1.583–13.710, $P=0.005$) were independent predictors. In model 3, TV > 7 ml (HR 2.737; 95%CI, 1.380–5.428, $P<0.001$) and GS ≥ 8 (HR 4.803; 95%CI, 1.615–14.279, $P=0.005$) were independent predictors. Model 3 resulted in a higher AUC (AUC 79.88%; 95%CI, 71.47–88.29%) compared to model 1 (AUC: 74.59%; 95%CI: 65.79–83.38%) ($P=0.033$).

Conclusions:
We identified TV cut-off > 7 ml as an independent predictor of CF in high-risk prostate cancer patients. Patients with a TV > 7 ml might potentially be considered candidates for a multi-modal, combined approach.

**P0995**
Preferences for the management of androgen deprivation-induced osteoporosis and metabolic syndrome in prostate cancer patients: A European web-based survey
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Introduction & Objectives: To assess the preference for the management of androgen deprivation-induced osteoporosis and metabolic syndrome in prostate cancer (PCa) patients among physicians in Europe through a web-based survey.

Material & Methods: The survey was conducted between 16 January and 15 June 2015 by the members of the Prostate Cancer Working Group of the Young Academic Urologists Working Party of the European Association of Urology. The 29-item questionnaire was designed through expert opinion by members of the working group. Dissemination of the survey was done through various channels; EAU newsletter, ESTRO newsletter, European national urological societies and during the EAU congress. There was no incentive for the respondents to complete the survey. Descriptive statistics were used. Non-European physicians and physicians without experience with ADT were excluded from the analysis.

Results: In total 546 respondents completed the survey of which 61 were excluded. Figure 1 shows the ADT-induced side-effects routinely communicated to patients before starting ADT. Half of the physicians provide the patient with educational material about these complications. Osteoporotic, metabolic and cardiovascular side-effects are communicated in 61%, 40% and 30% of patients with only 1/4 physicians performing a risk assessment prior to commencing ADT. A minority of physicians does not take preventive measures for osteoporotic and metabolic consequences (15%). Calcium and vitamin D supplementation is prescribed by 69% of the physicians. To prevent metabolic consequences lifestyle advice is the most popular measure (71%) followed by the tobacco cessation advice (31%) and enrollment in a supervised exercise program (22%). The low inclusion of patients in exercise programs is explained by the low availability of such programs throughout Europe (25%), although 3/4 physicians believe in its positive effects. The majority of the physicians also believe in the role of a dietician (65%).

Conclusions: Patients are not well informed about the risk of ADT induced osteoporosis and metabolic syndrome and they rarely undergo a risk assessment prior to the start of ADT. Nevertheless, physicians do provide adequate preventive measures in the majority of patients.
**P096**

**Standard practice compared to evidence based strategies for the management of androgen deprivation-induced side effects in prostate cancer patients: A European web-based survey**


**Introduction & Objectives:** To compare standard practice patterns in the management of androgen deprivation therapy (ADT)-induced side-effects with evidence based strategies through a European web-based survey.

**Material & Methods:** The survey was conducted between 16 January and 15 June 2015 by the members of the Prostate Cancer Working Group of the Young Academic Urologists Working Party of the European Association of Urology. Members of the working group designed the 29-item questionnaire through expert opinion. Dissemination of the survey was done through various channels; EAU newsletter, ESTRO newsletter, European national urological societies and during the EAU congress. There was no incentive for the respondents to complete the survey. Descriptive statistics were used. Evidence-based strategies were defined by Nguyen et al. [1]. Non-European physicians and physicians without experience with ADT were excluded from the analysis.

**Results:** In total 546 respondents completed the survey of which 61 were excluded. Figure 1 shows the evidence-based strategies physicians routinely apply for patients treated with long-term ADT. The majority of physicians apply at least one evidence-based strategy for the prevention and/or treatment of metabolic consequences and osteoporosis in their practice, but less than 10% of the physicians apply all evidence based strategies. Less than 1/3 of the physicians provide evidence-based strategies for sexual dysfunction (32%), fatigue (31%) and hot flushes (22%).

Medical management (PDE5-I, transurethral alprostadil) was the first line therapy for sexual dysfunction for 50% of the physicians. In addition more than half of the physicians never treat ADT-induced fatigue or hot flushes.

**Conclusions:** Physicians partially provide evidence-based strategies for the management of metabolic and osteoporotic side-effects. However, sexual dysfunction, fatigue and hot flushes are rarely adequately treated.

**Reference(s)**


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**Figure 1.** Evidence-based strategies physicians routinely apply in their practice with long-term ADT patients.

**Results:** In total 546 respondents completed the survey of which 61 were excluded. Figure 1 shows the evidence-based strategies physicians routinely apply for patients treated with long-term ADT. The majority of physicians apply at least one evidence-based strategy for the prevention and/or treatment of metabolic consequences and osteoporosis in their practice, but less than 10% of the physicians apply all evidence based strategies. Less than 1/3 of the physicians provide evidence-based strategies for sexual dysfunction (32%), fatigue (31%) and hot flushes (22%).

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**Conclusions:** Physicians partially provide evidence-based strategies for the management of metabolic and osteoporotic side-effects. However, sexual dysfunction, fatigue and hot flushes are rarely adequately treated.

**Reference(s)**


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**P097**

**Impact of enzalutamide (ENZA) compared with bicalutamide (BIC) on Quality of Life (QoL) in men with metastatic castration-resistant prostate cancer (mCRPC): Results from the TERRAIN study**


**Introduction & Objectives:** The TERRAIN trial (NCT01288911) compared efficacy and safety of ENZA 160 mg/day (n = 184) vs BIC 50 mg/day (n = 191) in asymptomatic/mildly symptomatic men with mCRPC who had progressed on luteinising hormone-releasing hormone agonists/antagonists (LHRHa) or after bilateral orchiectomy. The study showed that ENZA was superior to BIC in progression-free survival (PFS) and prostate-specific antigen (PSA) response rates. TERRAIN also prospectively evaluated QoL.

**Material & Methods:** QoL was assessed at baseline (BL) and during treatment (tx) using validated tools: FACT-P and EQ-5D. Mean changes from BL in QoL scores were analysed longitudinally using a mixed model repeated measures (MMRM) and a pattern mixture model (PMM) as exploratory analyses. Data up to Week 61 (W61) were used due to attrition in both arms. Clinically meaningful deterioration was defined by pre-established minimal important difference (MID) thresholds (Cella et al, VIH 2009; Pickard et al, HQLO 2007).

**Results:** Median tx duration was 11.7 months (ENZA) and 5.8 months (BIC). BL QoL scores were similar between arms. Decline from BL in QoL scores at W61 was lower with ENZA than BIC (table). Clinically relevant deterioration from BL (exceeded upper bound of MID range) in FACT-P scores was only seen with BIC (for 4 and 7 out of 8 scores in the MMRM and PMM analysis, respectively). Median time to 1st deterioration was longer with ENZA vs BIC for all outcomes except physical well-being (WB). Statistical significance (p < 0.05) was reached for EQ-5D utility index, FACT-G and FACT-P total scores.

**Conclusions:** In TERRAIN, in addition to PFS and PSA benefit, tx with ENZA generally resulted in better QoL and longer time to 1st QoL deterioration vs BIC, both reaching significance in several domains.
Bladder cancer

P098
Expression of androgen receptor in non-muscle-invasive bladder cancer predicts the preventive effect of androgen deprivation therapy on tumour recurrence

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Introduction & Objectives: We previously demonstrated that androgen deprivation therapy (ADT) for prostate cancer (PC) significantly reduced the risk of bladder cancer (BC) recurrence (hazard ratio: 0.29). However, whether the preventive effect of ADT on BC recurrence was mediated by androgen receptor (AR) signals remained unclear because most of the ADT patients received LHRH analogue which reduced serum levels of not only androgens but also estrogens. The purpose of this study is to show the associations between the expression of AR/estrogen receptors (ERs) in TUR specimens and BC recurrence in patients treated with ADT.

Material & Methods: We retrospectively retrieved 72 BCs and 42 corresponding normal urothelial tissues from patients who received ADT for PC in 2001–2012. We immunohistochemically stained the specimens for AR/ER(α/ER(β). Using Kaplan–Meier analyses and Cox proportional hazard models, we assessed the prognostic significance of AR/ER(α/ER(β) expression and other clinical variables for tumour recurrence.

Results: AR/ER(α/ER(β) were positive in 44(61%)/22(31%)/39(54%) tumours and 35(83%)/24(57%)/34(81%) corresponding normal urothelial tissues, respectively. There were no statistically significant correlations between AR/ER(α/ER(β) expression and clinicopathological features of BC. With a median follow-up of 31.3 months, 12 (43%) of 28 patients with AR(+) tumour versus 11 (23%) of 44 patients with AR(−) tumor experienced BC recurrence. Thus, patients with AR(+) tumour had a significantly lower risk of BC recurrence (P=0.031), compared with those with AR(−) tumour. Meanwhile, the expression of ER(α/ER(β) in tumours and that of AR/ER(α/ER(β) in normal urothelial tissues were not significantly correlated with recurrence. A multivariate analysis revealed AR positivity in tumours as an independent prognostic factor (hazard ratio: 0.31; 95% confidence interval: 0.11–0.82) for BC recurrence.
Table: Multivariate analyses for BC recurrence in ADT patients

<table>
<thead>
<tr>
<th>Variables</th>
<th>HR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, continuous</td>
<td>1.05 (0.96–1.15)</td>
<td>0.282</td>
</tr>
<tr>
<td>AR expression</td>
<td>0.23 (0.09–0.62)</td>
<td>0.003</td>
</tr>
<tr>
<td>Tumor grade (3 vs. 12)</td>
<td>1.42 (0.36–5.52)</td>
<td>0.615</td>
</tr>
<tr>
<td>pT stage (pT1 vs. pTa)</td>
<td>0.43 (0.09–2.00)</td>
<td>0.282</td>
</tr>
<tr>
<td>Tumor size (≥3 cm vs. &lt;3 cm)</td>
<td>1.74 (0.48–6.27)</td>
<td>0.396</td>
</tr>
<tr>
<td>Tumor number (multiple vs. single)</td>
<td>3.72 (1.33–10.41)</td>
<td>0.013</td>
</tr>
<tr>
<td>CIS (yes vs. no)</td>
<td>2.84 (0.37–21.90)</td>
<td>0.316</td>
</tr>
<tr>
<td>Intravesical instillation (yes vs. no)</td>
<td>0.38 (0.12–1.23)</td>
<td>0.106</td>
</tr>
</tbody>
</table>

Abbreviations: CIS, carcinoma in situ.

Conclusions: These results indicate that ADT prevents BC recurrence via the AR signals, but not ER(α)/ER(β) signals. LHRH analogue and anti-androgen monotherapy may thus be similarly useful. In addition, AR status may function as a predictor of the preventive effect of ADT in patients with non-muscle-invasive BC.

P099
Efficacy and safety of adjuvant atezolizumab (anti-PD-L1) vs observation in patients with muscle-invasive urothelial carcinoma of the bladder (IMvigor 010)
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Introduction & Objectives: Cisplatin-based neoadjuvant chemotherapy (NAC) followed by radical cystectomy is widely recommended for muscle-invasive bladder cancer (MBIC). There is no clear survival benefit for AC. Atezolizumab (atezo; MPDL3280A) is an anti-PD-L1 antibody that inhibits the binding of PD-L1 to PD-1 and B7–1. Atezo demonstrated a 50% unconfirmed response rate and manageable safety profile in patients (pts) with metastatic BC with higher levels of PD-L1 expression on tumor-infiltrating immune cells (IC; Petrylak, ASCO 2015, abstract 4501). Therefore, there is a strong rationale to test atezo in the adjuvant setting. IMvigor 010 (NCT02450331) is a Phase III open-label, multicenter, randomized, controlled study to evaluate the efficacy and safety of atezo adjuvant treatment compared with observation in pts with PD-L1-selected MBIC who are at high risk for recurrence following cystectomy.

Material & Methods: Pts will be randomized 1:1 to receive atezo (1200 mg intravenously every 3 weeks) or undergo observation as adjuvant treatment for up to 1 year. Pts will be stratified by number of lymph nodes resected, nodal status, tumor stage after cystectomy, age-adjusted Charlson Comorbidity Index and prior NAC. Inclusion criteria include histologically or cytologically confirmed MBIC, cystectomy with lymph node dissection and Eastern Cooperative Oncology Group performance status ≤2. Pts with prior NAC must have tumor staging of ypT2–T4a or ypN+. Pts without prior NAC must be ineligible for or have declined cisplatin-based AC and have tumor staging of pT3–T4a or pN+. PD-L1 expression on IC in cystectomy tumor specimens will be centrally assessed using the SP142 immunohistochemistry (IHC) assay. Pts with a PD-L1 IHC score of IC2/3 (IC ≥5% PD-L1+) are eligible. The primary efficacy endpoint is disease-free survival. Secondary efficacy endpoints are overall survival, disease-specific survival and distant metastasis-free survival. The safety objective is to evaluate the safety and tolerability of atezo in the adjuvant setting. The exploratory objective is to assess predictive, prognostic and pharmacodynamic biomarkers. Disease recurrence will be determined by the investigator based on radiographic evidence with the support of available biopsy results. Approximately 440 pts will be enrolled globally. This trial is currently enrolling. For more information on this trial and other ongoing atezo clinical trials, please visit www.ClinicalTrials.gov.

P100
NBI (Narrow Band Imaging) assisted cystoscopy: when, how and in which patients is an effective tool
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Introduction & Objectives: WL (White Light Cystoscopy) is still considered the gold-standard and the most cost-effective method to detect the bladder cancer. Sometimes it fails to detect bladder lesions, especially when the cancer anatomy is not as usual. NBI improve visualization of bladder tumours even if specificity reported in literature (75–77%) is slightly lower compared with WL (72–83%). We evaluated the role of NBI-cystoscopy (NBI-C) in the outpatient setting.

Material & Methods: This is a prospective, comparative, non-randomized trial, recording the differences between the NBI-C and WL in all patients scheduled for cystoscopy. At this stage we report an interim analysis. For each procedure two urologist have been involved and a WL was performed by the first investigator, followed by the second urologist performing the NBI-C and blinded to the first observer results. Switching between WL and NBI was achieved by pushing a button on the head of the scope. All suspicious lesions were described in size, number and shape and were recorded on a standard bladder diagram. In every patients with suspicious lesions a cytology sample from bladder wash out (BWO) was collected, and all patients with positive cytology or visible abnormalities were scheduled for TUR-T. The instrument used for this study was the Olympus Flexible Video Cystoscope CYF-VH. All the statistics analysis were performed with “IBM SPSS Statistics” software.

<table>
<thead>
<tr>
<th>Category</th>
<th>Cytology</th>
<th>Negative</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>By WLI</td>
<td>By NBI</td>
<td>By WLI</td>
</tr>
<tr>
<td>Bladder cancer FU</td>
<td>58 (32.2%)</td>
<td>48 (26.7%)</td>
<td>44 (24.4%)</td>
</tr>
<tr>
<td>Hematuria</td>
<td>21 (11.7%)</td>
<td>13 (7.2%)</td>
<td>12 (6.7%)</td>
</tr>
<tr>
<td>LUT</td>
<td>9 (5%)</td>
<td>9 (5%)</td>
<td>2 (1.1%)</td>
</tr>
<tr>
<td>LUTS</td>
<td>23 (12.8%)</td>
<td>21 (11.7%)</td>
<td>2 (1.1%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.5%)</td>
<td>0</td>
<td>8 (4.4%)</td>
</tr>
<tr>
<td>Positive cyt</td>
<td>17 (100%)</td>
<td>17 (100%)</td>
<td>16 (100%)</td>
</tr>
<tr>
<td>Atypic cells</td>
<td>8 (50%)</td>
<td>16 (100%)</td>
<td>16 (100%)</td>
</tr>
<tr>
<td>Inflammatory cells</td>
<td>12 (75%)</td>
<td>16 (100%)</td>
<td>16 (100%)</td>
</tr>
<tr>
<td>Negative</td>
<td>21 (40.4%)</td>
<td>27 (51.9%)</td>
<td>20 (11.1%)</td>
</tr>
</tbody>
</table>

Results: At date, a total of 184 patients were enrolled and in 4 cases was impossible to perform a cystoscopic evaluation (1: Active hematuria; 3: Urethra stricture). 180 patients were evaluated; a total of 246 lesions were identified by NBI and WL. The median number was 2.76 for NBI and 2.02 for WL. 108/246 (43.9%) of lesions were identified by NBI and 138 by both techniques. NBI and WL (NBI+/WL−) were discordant in 21.4% of positive cases. All sites identified by both techniques were confirmed by WLI. 108/246 (43.9%) of lesions were identified by NBI and WLI. The median number was 2.76 for NBI and 2.02 for WLI. The patients were divided in 5 different “group of indications”: Bladder Cancer Follow-up (102/56.7%); Hematuria (33/18.3%); RUT (116.1%);
LUTS (25/13.9%); other (9/5%). Cytology samples were collected from 101 patients and were classified by our pathologist as: positive (17/16.8%); negative (52/51.4%); atypical cells (16/15.8%) and inflammatory (16/15.8%). In the table we describe the statistics characteristics of our group.

Conclusions: Our study, according with the literature's data, confirm that NBI-C, compared with WLI improves the detection rate of suspicious bladder lesions without increasing the healthcare cost and toxicity for the patients. Also we suggest to use NBI as a “supplement” to standard WLC, especially in patients with BC history, hematuria and atypical cytology pattern. In the future further RCT will confirm the property of NBI assisted cystoscopy in the bladder cancer.

P101
Effects of Hippophae rhamnoides extract on mucosal injury (mucositis) induced in rat jejunum with cisplatin
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Introduction & Objectives: Cisplatin is a broad-spectrum, non-cycle specific, platinum derived chemotherapeutic drug used in treatment of various solid cancers such as advanced bladder cancer and metastatic testicular tumours. Mucositis which is seen during chemotherapy is an important dose limiting toxicity in the treatment of malignant diseases. Free oxygen radicals (ROS) formation and DNA damage are observed in the pathobiology of mucositis in the initial stage. Then, proinflammatory cytokines such as tumour necrotizing factor-α (TNF-α) and interleukin-1β (IL-1β) release by endothelial epithelial cells. Eventually, tissue damage and ulceration develop and mucosa becomes prone to bacterial contamination. Cisplatin was reported to produce mucositis by oxidative stress. Based on this information from the literature, it was understood that drugs which are capable to show combination of antioxidant, antiulcer, antitoxic and antimicrobial activities might be beneficial for treatment of cisplatin-induced mucositis.

We aimed to investigate effects of Hippophae rhamnoides extract (HR) against experimental jejunal mucositis induced in rats with cisplatin, at biochemical, histopathological and gene expression levels.

Material & Methods: Animals were divided into healthy (HG), HR+cisplatin (HRC) and cisplatin control (CCG) groups. After 1 hour of administration of HR 50mg/kg (n-6) orally to the HRC and distilled water as solvent to the CCG and HG groups, HRC and CCG groups were injected with a single dose intraperitoneal (ip) cisplatin. HR and distilled water were given once a day for 7 days. At the end of this period, all the animals were killed with high dose anesthesia. The levels of malondialdehyde (MDA), nitric oxide (NO), total glutathione (tGSH), glutathione s-transferase (GST), glutathione peroxidase (GPO) and catalase (CAT) and IL-1β, TNF-α gene expression were measured in the jejunal tissue and histopathologic examination was performed.

Results: Biochemical results: HR significantly inhibited increase of oxidants such as MDA and NO, and decrease of antioxidants such as tGSH, GST, GPO and CAT due to cisplatin in the jejunal tissue. Gene expression results: Cisplatin significantly increased IL-1β and TNF-α in the jejunal tissue compared to the HG group. However, IL-1β and TNF-α gene expressions in the group administered HR were almost at the same level with those of HG. Histopathological examination of jejunal revealed that HR prevents hemorrhage, inflammatory cell infiltration and the loss of severe villous surface epithelium caused by cisplatin.

Conclusions: HR reversed oxidative stress caused by cisplatin in the jejunal tissue. These results suggest that, HR might be beneficial in prophylaxis of jejunal injury due to cisplatin chemotherapy.

P102
A phase II, single-arm study of Nivolumab in patients with metastatic or unresectable Urothelial cancer who have progressed following treatment with a platinum agent
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Introduction & Objectives: Clinical trials in patients with advanced bladder cancer have reported response rates of up to approximately 30% and 60% with single-agent and multi-agent regimens, respectively, and minimal improvements in survival over best supportive care. Guidance on second-line treatment options is unclear and no global standard exists. Nivolumab, a fully human IgG4 programmed death-1 (PD-1) immune checkpoint inhibitor antibody, has clinical activity in multiple tumour types. Safety and activity will be evaluated in a phase II/III, open-label study of nivolumab alone or in combination with ipilimumab in patients with advanced or metastatic solid tumours, including bladder cancer (NCT01928394). In a separate study and the focus of this abstract (NCT02387996), we will estimate the effect of nivolumab on tumour size and other safety and efficacy parameters in patients with unresectable or metastatic urothelial cancer progressing or recurring following platinum-based chemotherapy.

Material & Methods: This multinational study for advanced urothelial cancer patients, which started in March 2015, is expected to enroll as many as 250 patients and will be completed in October 2017. Eligible patients have metastatic or surgically unresectable urothelial carcinoma with measurable disease by imaging; disease progression or recurrence with ≥1 prior platinum-based regimen; and no liver metastases if >2 prior lines of chemotherapy were administered. Additionally, patients who had cystectomy for localized urothelial cancer along with disease recurrence or progression within 12 months of neo-adjuvant or adjuvant platinum-based treatment are eligible. Patients with active CNS metastases are excluded. Nivolumab monotherapy will be administered every 2 weeks until disease progression or unacceptable toxicity. The primary endpoint is objective response rate, and secondary endpoints include progression-free survival and overall survival. Further sub-analyses will be performed by programmed death-ligand 1 (PD-L1) tumour expression.
P103
Evans blue as a diagnostic tool for non-muscle-invasive bladder cancer
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Introduction & Objectives: Bladder cancer is a major health problem worldwide, and the fourth most common form of cancer in men, it is also very labor-intensive and costly to treat. At first diagnosis, approximately 75% of detected lesions are classified as non-muscle-invasive bladder cancer (NMIBC), originating from the urothelium. The primary treatment for NMIBC is the removal of cancerous tissue from the bladder, called transurethral resection (TUR), performed both as a diagnostic and therapeutic tool. After a first TUR, up to 30% to 80% of patients experience a recurrence of the disease and a variable amount of superficial lesions will eventually progress to invasive cancer. Therefore, accurate and early diagnosis of NMIBC is crucial for the treatment. The gold standard for the diagnosis of suspicious lesions during TUR is white-light (WL) cystoscopy. In general, this technique works well in the detection of exophytic lesions, but small papillary lesions and flat lesions such as carcinoma in situ are underdiagnosed.

To investigate the possibility of using Evans blue (EB) as a novel diagnostic tool to detect bladder tumors with WL cystoscopy, in a preclinical study we examined the biodistribution of the compound in different layers (urothelium, submucosa, muscle) of a normal rat bladder and in a rat bladder bearing a malignant urothelium composed of syngeneic AY-27 tumor cells.

Material & Methods: EB was instilled into both normal as well as tumor-bearing rat bladders. Following instillation, bladders were removed and snap frozen in liquid nitrogen. The distribution of EB in the different layers was quantified using fluorescence microscopy. To gain more insight into the mechanism underlying the selective accumulation of EB in tumor tissue, bladder sections were prepared for ultrastructural investigations by means of transmission electron microscopy. Besides, we also examined the expression of E-cadherin, claudin-1 and desmoglein-1 by immunohistochemistry to study the integrity of the bladder wall as these molecules are key constituents of adherens junctions, tight junctions and desmosomes, respectively.

Results: In most cases the accumulation of EB in malignant bladders was substantially higher than in healthy bladders, at least when 1 mM EB instillations were used. In case of a 1 mM EB instillation for 2 hrs, the EB-associated fluorescence in malignant urothelial tissue was 55 times higher as compared to the fluorescence found in normal urothelium. Ultrastructurally, malignant tissue displayed wider intercellular spaces and a decreased number of cell junction components as compared to normal tissue, pointing to defects in the urothelial barrier. No differences in expression of E-cadherin were found, whereas desmoglein-1 staining was stronger in the membranes of healthy bladder urothelium compared to tumor tissue. Claudin-1 expression was negative in all samples tested.

Conclusions: EB is selectively taken up by tumor tissue after intravesical instillations in rats bearing bladder tumors. The lower expression of desmoglein-1 in tumor samples, together with the decreased presence of desmosomes observed with TEM, likely imply that desmosomes play an important role in the ultrastructural differences between healthy rat urothelium and tumor tissue, and secondary to that, to the differential uptake of EB in both tissues. We believe that our findings can be useful for future clinical developments in the field of diagnostics for bladder cancer.

P104
Urothelial bladder pT0x tumours. How to predict positivity of the immediate second TUR

Introduction & Objectives: Current guidelines recommend a second TUR if there is no muscle in the specimen after initial resection. Re TUR represents a second surgical manoeuvre on these patients who usually have other comorbidities and increases risk of surgical and post operative complications. In our series up to 73% of the Re TURs are negative. The aim of this study is to better select those patients who really need Re TUR based on initial tumour features, age and comorbidities.

Material & Methods: Re TUR was performed in 55 patients from 154 with diagnosed pT0x (from January 2010 to June 2013). It took place 4–8 weeks after first resection. Main significant criteria to decide Re TUR from those not re-resected were: age (younger), ASA-I/II, Solid pattern, Tumour size (>1 cm) and High Grade. CIS presence was always re-rectected after BCG induction according to our protocols. To analyse how to predict positive pathology versus pT0/low grade of second TUR, univariate and multivariate logistic regression analysis was performed. Variables included were those with significant different values between both groups: Age, High grade, Solid pattern, Single/multiple and Tumour Size.

Results: 72.7% of Re TURs were negative. Positive cases were 15: 3 pT2, 3 pT0, 5 pT1 HG (1 pT1a and 4 pT1b/c), 3 CIS and 1 pT1 LG (it was included in pT0 group). Multivariate analysis showed that age (p < 0.01), multiple tumour (p 0.04) and tumour size (>1 cm) (p 0.05) were independent predictors for ReTUR positivity after initial pT0x diagnosis.

Conclusions: Immediate second TUR should be mandatory after initial pT0x in older patients, when multiple tumours, or with lesions above 1 cm size. These variables should be considered when building a nomogram that helps us to decide which patients may really benefit from Re TUR avoiding unnecessary re-interventions.

P105
Preliminary results of “TEMPOVISIO” study: Evaluation of confocal laser Micrscopy on per-operative evaluation of surgical margins in urothelial tumours

Introduction & Objectives: The Surgical margins analysis during radical cystectomy for urothelial carcinoma may be time consuming. Frozen section are sometimes repeated in case of doubt or poor quality of histological sample. The Confocal Laser Microscopy (CLM) could be used to evaluate in real time the surgical margins. In the present study, we evaluated ureteral surgical margins during radical cystectomy for urothelial carcinoma.

Material & Methods: In this prospective monocentric study, we used the Cellvizio® laser confocal system with a gastroflex B fiber. CLM of the ureteral was obtained after instillation of fluorescein 0.1% (Figure 1). CLM images are acquired as video sequences at rate of 12 frames per second with a resolution of 1 micron.

Criteria of evaluation are the existence of normal urothelium with specifically umbrella cells. The quality of sample is evaluated for the analysis for frozen section.
were negative. We observed 127 (12.1%) bladder neoplasms in we identified 234 patients (14.8%) with visible lesions only In our experience, we observed an overall suspicious bladder

Results: From September 2014 until June 2015, eight patients underwent radical cystectomy for urothelial carcinoma. For each uretere the mean CLM time was 5.5 minutes (range 4–7). The normal urothelium could be observed in all of 16 CLM during the 8 radical cystectomies. The existence of umbrella cells arranged closely (Figure 2) was always correlated with normal urothelium in histology analysis.

Conclusions: We concluded that the CLM could be helpful and quick to check surgical margins. More case of pathological margins are necessary to evaluate CLM in order to give specificity and sensitivity of this new device.

P106
Predictive power of NBI versus standard cystoscopy before TURB

Introduction & Objectives: The aim of this study was to evaluate, in the same patient before TURBT, the probability to increase our ability to detect bladder cancer comparing the predictive power NBI visible lesions cystoscopy versus white light visible lesions cystoscopy.

Material & Methods: From June 2010 to April 2012, 797 consecutive patients, 423 male and 374 female, affected by primitive, recurrent or suspicious bladder lesions, underwent WL plus NBI cystoscopy and following WL-TURB with bipolar Gyrus PK. All patients underwent preoperative standard white light cystoscopy: Topography and characterization of neoplasms and suspicious lesions followed by a similar evaluation using NBI. Subsequently all the patients underwent WL resection (WL-TURB) of the previously identified lesions. All the removed tissue was sent separately for histological evaluation.

Results: A total of 797 patients were enrolled in this study. In our experience, we observed an overall suspicious bladder lesions detection rate equal to 1571 bladder lesions. Overall, we identified 234 patients (14.8%) with visible lesions only at NBI. After the WL-TURB, we observed 1051 (66.8%) neoplastic lesions of the bladder; among them 521 (33.1%) were negative. We observed 127 (12.1%) bladder neoplasms in 99 patients (19.8%, p < 0.05), with negative WLJ and positive NBI cystoscopy.

The use of WL and NBI cystoscopy allowed us to have a sensitivity of 80.66% and of 97.85% with a PPV of 68.49% and of 63.74%, respectively. Regarding the accuracy, we observed a 63.74% and a 62.86% respectively. Staging (CIS, p < 0.05), grading (LG, p < 0.05), focality (unifocal, p < 0.05) and dimensions (<3 cm, p < 0.05) were statistically significant too.

Conclusions: After NBI cystoscopy, we observed an overall increased suspicious bladder lesions detection rate by 24.34% (194 pts.) and a bladder tumours NBI positive detection rate by 12.1% (99 pts.). Overall false positive detection rate was 35.75% (285 pts.). The combination of white light and NBI cystoscopy and subsequently bipolar TURBT seems to allow a better diagnostic and therapeutic approach to bladder tumours, especially in CIS lesions, LG lesions, primitive, unifocals and <3 cm lesions. The high rate of false positives could depend on artefacts produced during white light endoscopy.

P107
Our experience with NBI. Can it improves our ability to identify bladder tumours progression in the follow-up?

Introduction & Objectives: Although NMIBC is usually not life-threatening in the early stage, more than half of these tumours will relapse and approximately 10% to 20% of these tumours will develop into muscle-invasive bladder tumours. Aim of this study was to evaluate if use of light NBI (repeat NBI-assisted TURBT), during the follow-up, can lead advantage to identify undetected residual tumours following WL-TURBT.

Material & Methods: From June 2010 to April 2012, 797 patients – 423 male and 374 female – affected by primitive, recurrent or suspicious bladder lesions, underwent WL plus NBI cystoscopy and following WL-TURB with bipolar Gyrus PK. Of those, 512 presented a oncological bladder lesions and 444 pts, in according with EAU guidelines, were submitted to a 12 month’s follow up.

After performed WL TURBT 6 risk factors were assessed: Tumour size (cm), number of tumours, recurrence rate within one year, staging (T), grading (G), and CIS. Then, basing on mentioned factors and using the EORTC scoring system, the total score for recurrence for each patient was calculated separately. According to the total score, patients were divided into 4 recurrence risk groups. Patients with total recurrence score 0 were classified to group I, 2–6 points to group II, 7–13 to group III, and 14–23 to group IV risk of recurrence. Every three months, we performed a WLTURBT and a repeat NBI assisted TURBT on any suspected lesion (or scar), on our relative margins to present a persistent progression disease following repeat NBI assisted TURBT eleven patients (2.48%) had progression to muscle invasion bladder lesions, while after repeat NBI assisted TURBT eleven patients (2.48%) developed progression to pT2 bladder tumour in 12 months of follow-up. Of those, all lesions were localized in the bottom. Regarding to stratification in EORTC risk progression group we observed that 41.6% and 58.3% were II, and IV groups respectively. The high risk groups presented an elevated risk to present a persistent progression disease following repeat NBI assisted TURBT than low and intermediate risk groups. Stratifying these data for staging (pT) and grading, we observed a progression to pT2 in 16.6% pTaLG, and pTaHG, in 58.3% pT1HG and in 8.3 pCISHG, respectively.
If we evaluate the progression, as an increasing recurrence in staging and grading of the primary lesion but always non-muscle invasive, in the analyzed group within one year occurred in 265 patients (59.6%). The risk of bladder tumour progression was statistically more frequent in intermediate-risk group. The recurrence rate was 0%, 18.8%, 45.6%, and 35.4% in I, II, III and IV progression risk group, respectively. In a multivariate analysis, focality (p < 0.05) was a significant predictor to progression than status (p = 0.35) and dimensions (p = 0.43).

The overall time to progression following repeat NBI assisted TURBt in patients with to progression to pT2 than only upgrading staging and grading was 3.7 months.; thus on buttom upgrading staging and grading was 3.29 and 6.41, respectively.

Conclusions: Repeat NBI assisted TURBt allows a statistically significant advantage in identifying progression undetected residual tumours following WL-TURBT. Focalities was a significant predictor to progression.

P108
Urinary exosomes: Promising biomarkers for urothelial bladder cancer
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Introduction & Objectives: Exosomes represent a kind of extracellular vesicles (EVs) that are released by many different cell types. Exosomes containing specific proteins, lipids, mRNAs and miRNAs, have emerged as potent intercellular communicators. In a tumoral milieu these EVs can alter the extracellular matrix promoting tumoral progression and represent a source of potent non-invasive biomarkers since they can be isolated form different kind of fluids (urine, blood, bronchoalveolar lavage, cerebrospinal fluid, etc.). Our objective was to determine possible markers of tumour aggressiveness in patients with urothelial carcinoma of the bladder by extracting small RNAs from exosomes isolated from urine samples.

Material & Methods: Exosomes were isolated from urine of patients with urothelial bladder cancer. Patients with low grade urothelial carcinoma (n = 9). Patients with high grade urothelial carcinoma (n = 10) and healthy donors (n = 5). We performed mass spectrometry and miRNA arrays in order to find differences in the tumour profile, namely, miRNA expression. The results were tested with Western blot and Polymerase chain reaction.

Results: We found that miRNA 375 was down expressed in high grade urothelial carcinoma when compared to low grade urothelial carcinoma or healthy donors. We also found that the miRNA 146 profile is significantly affected in low grade urothelial carcinoma when compared to high grade urothelial carcinoma or healthy donors.

Conclusions: Bladder cancer is a complex and heterogeneous tumour. The study of urinary exosomes is a promising field of research in order to understand tumour behaviour, hence tumour progression. Our results point to miRNA 375 and miRNA 146 as two possible biomarkers of aggressiveness. More patients are needed in order to extract more robust conclusions and confirm the use of other miRNAs as biomarkers in Bladder cancer.

P109
Variations in pelvic lymph node dissection in clinical stage I–III bladder cancer: A Dutch nationwide population-based study
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Introduction & Objectives: To assess temporal tends in radical cystectomy (RC) and pelvic lymph node dissection (PLND) in the Netherlands between 2006 and 2012.

Material & Methods: This nationwide, retrospective, population-based study included clinical stage I–III bladder cancer (BC) patients (cT1–4aNOM0) from the Netherlands Cancer Registry who underwent RC as primary treatment for urothelial carcinoma between 2006 and 2012. Performance rates of PLND at RC, median lymph node count (LNC) and rates of positive nodal (pN+) disease were determined per year and their relation with pN+ disease during the study period was analysed. Furthermore patient and hospital characteristics associated with the performance of PLND at RC were identified.

Results: In total, 3678 patients were included. Mean age was 66.7 year and 75.6% (n = 2780) were male. Of all RCs, 49.8% (n = 1833) was performed in non-teaching hospitals. Clinical stages of disease were evenly distributed over the study period. Ninety percent (n = 3312) underwent RC plus PLND, with a median LNC of 10. Performance rate of PLND increased from 82.9% in 2006 to 95.6% in 2012 (p < 0.001), median LNC increased from 6 to 12 (p < 0.001) and the amount of pN+ disease increased from 17.4% to 23.0% (p < 0.001), Table 1. In academic hospitals (and 2 cancer centers) PLND was only omitted in 5.5%, vs. 9.5% and 12.4% in teaching and non-teaching hospitals, respectively (p < 0.001). Median LNC was 15.0 in academic hospitals vs. 10.0 and 9.0 in teaching and non-teaching hospitals, respectively (p < 0.001). Multivariate logistic regression analysis revealed females (Ref. male) and elderly patients (>70 yr.) (Ref. <50yr.) were less likely to receive a PLND. Patients operated in academic hospitals were more likely to receive a PLND (Ref. non-teaching hospital), as well as those operated after 2007 (Ref. 2006). All p20/ yr.) did not influence the chance of receiving PLND. Limitations: Extent of PLND was not registered.

Table 1. Distribution of clinical stages of disease and the performance of PLND, with corresponding median lymph node counts and rate of node positive disease over time

<table>
<thead>
<tr>
<th>Year</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RC, N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>424</td>
<td>419</td>
<td>522</td>
<td>510</td>
<td>524</td>
<td>588</td>
<td>537</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical stage, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>11.3</td>
<td>14.3</td>
<td>13.4</td>
<td>13.3</td>
<td>9.5</td>
<td>13.6</td>
<td>12.4</td>
<td>0.088</td>
</tr>
<tr>
<td>II</td>
<td>73.3</td>
<td>74.7</td>
<td>73.0</td>
<td>70.6</td>
<td>75.6</td>
<td>71.6</td>
<td>75.6</td>
<td>(chi-square)</td>
</tr>
<tr>
<td>III</td>
<td>15.3</td>
<td>11.0</td>
<td>13.6</td>
<td>16.1</td>
<td>14.9</td>
<td>14.8</td>
<td>13.4</td>
<td></td>
</tr>
<tr>
<td>PLND, %</td>
<td>82.9</td>
<td>84.3</td>
<td>89.9</td>
<td>88.3</td>
<td>91.1</td>
<td>95.4</td>
<td>95.6</td>
<td></td>
</tr>
<tr>
<td>Median LNC</td>
<td>7.0</td>
<td>8.0</td>
<td>9.0</td>
<td>9.0</td>
<td>11.0</td>
<td>13.0</td>
<td>12.0</td>
<td></td>
</tr>
<tr>
<td>pN+, %</td>
<td>17.4</td>
<td>17.4</td>
<td>17.4</td>
<td>20.6</td>
<td>21.1</td>
<td>20.2</td>
<td>23.0</td>
<td></td>
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</tbody>
</table>

Conclusions: In the Netherlands, the performance of PLND at RC and LNC has significantly increased during the period 2006 and 2012. This suggests improved pathological staging of clinical stage I–III BC.
P110
Functional evaluation of Moeen’s modification of Studer ileal neobladder
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Introduction & Objectives: To evaluate the results of our modification in the reconstruction of Studer ileal neobladder after radical cystectomy.

Material & Methods: Radical cystectomy and Studer ileal neobladder was performed in 60 patients for invasive bladder cancer. Only 40 cm segment of the intestine was used; 32 cm segment for constructing the body of the neobladder, while the remaining 8 cm was used as an isoperistaltic intact limb for ureteral reimplantation (Moeen’s modification). Evaluation included clinical, laboratory, radiographic and urodynamic studies to determine the functional and oncological outcomes.

Results: Early complications occurred in 6 patients (10%). According to the modified Clavien system, two patients had grade I complications, grade IIIa and IIIb each occurred in one patient and two patients had grade V complications. Late complications (5.2%) included incisional hernia in 2 patients and intestinal obstruction in 1. Daytime and nighttime continence was 93.1% and 89.7% respectively. Reflux was observed in 6 patients (10.2%) which was unilateral in 3 patients and bilateral in 3 without affecting the renal functions.

Conclusions: Minimizing the length of the ileum for Studer neobladder reconstruction using Moeen’s modification is feasible and with acceptable results.

P113
Uretero-sigmoidostomy in 2015; does it still have a place?
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Introduction & Objectives: To declare the indications of uretero-sigmoidostomy after radical cystectomy in modern urology.

Material & Methods: Between January 2004 and December 2013, 1080 radical cystectomies followed by uretero-sigmoidostomy were performed out of all urinary diversion procedures in our center. We retrospectively revised the indication of this operation in those patients. At the time of abstract submission, 501 (46.4%) patients are still alive. Evaluation included clinical and radiographic studies to determine the functional and oncological outcomes.

Results: The age range was 38–71 years. 820 patients (75.9%) were males and 260 (24.1%) were females. Early complications occurred in 179 patients (16.5%). According to the modified Clavien system, it was Grade I in 55 patients, grade II in 43, grade IIIa in 22, IIIb in 19, grade IVa in 12, grade IVb in 9 and grade V in 19 patients. Late complications occurred in 389 (36%) patients. Daytime and nighttime continence were 88.8% and 86% respectively. Indications of uretero-sigmoidostomy were bladder neck tumors in markedly obese patients (BMI ≥40 kg/m²), previous multiple ileal resections, patients with multiple co-morbidities, intraoperative difficulties nesissicating rapid termination of the procedure, patients refusing the ileal conduit and those with physical or mental impairment who could not care with either the neobladder or the ileal conduit.

Conclusions: Inspite of being the least desired form of continent urinary diversion, uretero-sigmoidostomy still serves a larger number of patients in our country either due to advanced stage at presentation or in patients refusing the ileal conduit due to cultural and psychological purposes.

P114
Pure intracorporeal laparoscopic radical cystectomy with orthotopic “U” shaped ileal neobladder

Introduction & Objectives: Radical cystectomy with pelvic lymph node dissection represents the standard treatment for muscle-invasive, and high-risk non-muscle-invasive bladder cancers. Aim of this study was to report our case series of 30 patients undergoing totally laparoscopic radical cystectomy (LRC) with reconstruction of an intracorporeal orthotopic ileal neobladder. Intra- and perioperative results and the functional and oncological outcomes 9 months after operation are reported.

Material & Methods: Between October 2010 and December 2012, 30 male patients underwent LRC with a pure laparoscopic orthotopic ileal “U”-shaped neobladder diversion. The men had a median age of 67 years, a median body mass index of 22.3, and a mean ASA score of 2.2; they represented various clinical stages of disease.

Results: None of the patients required conversion to open surgery, and no perioperative mortalities were reported. The median operating time was 365 min, and the median blood loss was 290 mL, with a transfusion rate of 26.6%. All surgical margins were negative; 8 patients with non-organ-confined disease or positive lymph nodes received adjuvant chemotherapy. Early complications (within 30 days) occurred in 7 patients, and late complications occurred in 6 patients. The mean hospital stay was 9 days. At 9 months after surgery, the daytime continence rate was 83.3% and the night-time continence rate was 73.3%.

Conclusions: Pure LRC with intracorporeal orthotopic ileal neobladder reconstruction may represent a viable alternative to open radical cystectomy, with a significant reduction in patient morbidity. Future, large, randomized controlled trials with extensive follow-up are needed to confirm our encouraging results.

P115
Open versus laparoscopic radical cystectomy – experience in 193 patients in a non-academic hospital
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Introduction & Objectives: Laparoscopic radical cystectomy (LRC) is a technically high-demanding procedure requiring advanced laparoscopic skills. LRC aims to offer the benefits of a complete minimally invasive approach with equivalent oncologic outcomes of open surgery. LRC can be a cost-effective alternative for open radical cystectomy (ORC). We report our results of laparoscopic radical cystectomy in 122 patients with urethral cell cancer performed by a single surgeon (LF) in a non-academic centre and compare clinical outcome with the results of open radical cystectomy in 71 patients.

Material & Methods: From January 2005 till October 2014, 193 patients underwent a radical cystectomy for muscle invasive bladder cancer or BCG-resistant high-risk superficial bladder cancer. LRC was performed in 122 patients; 71 patients had an ORC. All the laparoscopic procedures were performed by the same urologist. The open procedures were performed by four experienced urologists. No patients were excluded for the laparoscopic approach, except when preoperative it was deemed not technically feasible. Patients who underwent an open procedure were diagnosed before 2008 or were preoperatively seen by urologists who only perform ORC and did not refer for the minimal invasive approach. Patient characteristics and operative data are reported. Data regarding patients who underwent LRC were prospectively collected. Data regarding
the ORC group were retrospectively collected from the medical records.

Results: Patient characteristics are comparable in both groups: Medium age of 68 years, mean BMI of 25 and mean Charlson comorbidity index of 3. Peri-operative outcome show differences in OR-time, blood loss and transfusion rate, hospital stay and need for ICU or MC admission (Table 1).

Post-operative (<90days) less major complications are seen in the LRC group, but without significant difference. Oncologic results are equal (Table 2). Overall survival after 4 years in the LRC group, but without significant difference.

Table 1, Peri-operative variables in our series

<table>
<thead>
<tr>
<th>Variable</th>
<th>LRC (N=122)</th>
<th>ORC (N=71)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, min</td>
<td></td>
<td></td>
<td>P&lt;0.00</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>358 (81)</td>
<td>294 (71)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>343</td>
<td>272</td>
<td></td>
</tr>
<tr>
<td>Blood loss, ml</td>
<td></td>
<td></td>
<td>P&lt;0.00</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>630 (589)</td>
<td>2171 (1268)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>400</td>
<td>2172</td>
<td></td>
</tr>
<tr>
<td>Hospital stay, days</td>
<td></td>
<td></td>
<td>P=0.011</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>17 (16)</td>
<td>22 (24)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>13</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Blood transfusion, n (%)</td>
<td></td>
<td></td>
<td>P=0.014</td>
</tr>
<tr>
<td>IC/MC transfer, n (%)</td>
<td>29 (23.8%)</td>
<td>28 (41.1%)</td>
<td></td>
</tr>
<tr>
<td>IC</td>
<td>19 (15.7%)</td>
<td>48 (69.6%)</td>
<td>P&lt;0.00</td>
</tr>
<tr>
<td>MC</td>
<td>18 (14.9%)</td>
<td>15 (21.7%)</td>
<td>P&lt;0.237</td>
</tr>
<tr>
<td>Ward</td>
<td>84 (69.4%)</td>
<td>6 (8.8%)</td>
<td>P&lt;0.00</td>
</tr>
</tbody>
</table>

Table 2. Oncologic outcome in our series

<table>
<thead>
<tr>
<th>Variable</th>
<th>LRC (n=122)</th>
<th>ORC (n=71)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathological stage</td>
<td></td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>pT0</td>
<td>18 (14.8%)</td>
<td>16 (22.5%)</td>
<td></td>
</tr>
<tr>
<td>pT1</td>
<td>16 (13.1%)</td>
<td>7 (9.9%)</td>
<td></td>
</tr>
<tr>
<td>pTis</td>
<td>10 (8.2%)</td>
<td>4 (5.6%)</td>
<td></td>
</tr>
<tr>
<td>pT2</td>
<td>22 (18%)</td>
<td>8 (11.3%)</td>
<td></td>
</tr>
<tr>
<td>pT3</td>
<td>39 (32%)</td>
<td>19 (26.8%)</td>
<td></td>
</tr>
<tr>
<td>pT4</td>
<td>17 (13.9%)</td>
<td>5 (7%)</td>
<td></td>
</tr>
<tr>
<td>Total lymph nodes</td>
<td></td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>15 (6)</td>
<td>11 (7)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>15</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Positive lymph nodes</td>
<td>31/122</td>
<td>12/59</td>
<td>NS</td>
</tr>
<tr>
<td>Positive surgical margins</td>
<td>15/122</td>
<td>8/58</td>
<td>NS</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>27/96</td>
<td>13/49</td>
<td>NS</td>
</tr>
</tbody>
</table>

Conclusions: Our data suggest that LRC is a safe and minimally invasive alternative to ORC with significant benefits: Less blood loss and blood transfusions, reduction of ICU admission and hospital stay, while preserving equal oncological outcomes compared to ORC in our department. Longer follow up is needed to evaluate the oncological outcome, still the mid-term outcome of both techniques is equivalent.

P116 Neoadjuvant sorafenib, gemcitabine, and cisplatin (SGC) for muscle-invasive urothelial bladder cancer (UBC): Updated clinical and translational findings of an open-label, single group, phase 2 study

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Introduction & Objectives: After cystectomy, >40% of patients (pts) with muscle-invasive UCB (MIUBC) will develop a recurrence. Despite neoadjuvant chemotherapy is recommended, a minor survival benefit compared to cystectomy alone is deemed. SGC combination is an open-label, single-group, phase 2 trial (NCT01222676).

Material & Methods: Patients with T2-T4a N0 UBC received 4 cycles of cisplatin 70mg/m^2 day 1, and gemcitabine 1000mg/m^2 day 1 and 8, q3 weeks. Sorafenib 400 mg q12h was administered daily from day 1 until radical cystectomy. Intention-to-treat analysis was applied. In a Simon’s 2-stage design, 45 pts will be accrued and the rate of pathologic complete responses (pT0) is the primary endpoint. Residual carcinoma in situ was considered as pT0. The treatment will be considered active with ≥14 pT0, assuming Ho: ≤0.20 and H1: ≥0.40 (Type I and type II error of 5% and 10%). Molecular characterization of responders is planned through Next Generation Sequencing (NGS). DNA was isolated from FFPE of TURB samples using the GeneRead DNA FFPE kit™ (Qiagen). Ion AmpliSeq™ Comprehensive Cancer Panel (Life Technologies) was utilized, targeting the coding sequences of 406 genes, the Ion AmpliSeq Library Kit2.0™ and the Ion Torrent Personal Genome Machine™ platform (Life Technologies).

Results: 37 pts were enrolled from 04/11 to 03/15. Median age was 61yrs (IQR: 54–66). 24 (64.9%) had T2, 12 (32.4%) T3, and one a T4. 9 (24%) pts had hydronephrosis. 22 (59.4%) pts had a macroscopical disease before SCC (including biopptic TURB in 9 pts). 34 completed the treatment and are evaluable for the primary endpoint. 17/23 RECIST-evaluable pts had a partial response.

Conclusions: Pending the completion of accrual, the primary endpoint was met. SGC combination is tolerable and endowed of antitumour activity in MIUBC. NGS might provide insights into the relevant biology of responders, and mature results will be presented.
P117
Prescribing platinum chemotherapy based on glomerular filtration rate using wright formula instead of surgical safety and efficacy, perioperative morbidity, histological assessment and tumours (NMIBT) from the perspectives of surgical safety and targeted medium size papillary non-muscle invasive bladder transurethral resection of bladder tumours (TURBT). The study included 260 patients with at least 1 bladder tumour ≥3cm based on abdominal ultrasound, contrast CT and flexible cystoscopy, subsequent to visually complete tumour ablation. A similar mean tumour size was determined in the 2 series (1.8 versus 1.7 cm). By comparison to classical TURBT, a significantly reduced rate of obturator nerve reflex adverse event causing bladder wall perforation was encountered (1.7% versus 8.3%). Moreover, significantly decreased mean operation time (9.4 versus 17.1 minutes) and hemoglobin level drop (0.3 versus 0.8 g/dl) were emphasized among en-block resection cases. Also, substantially decreased mean catheterization period (1.6 versus 2.7 days) and hospital stay (2.1 versus 3.4 days) were determined in the en-block study arm. The pathological analysis confirmed the presence of detrusor muscle in the resected biopsy specimens for all enrolled patients, thus enabling a reliable tumour staging to be established. During the 1 year follow-up, a significantly lower recurrence rate was found in the en-block group (3.8% versus 13.5%), mainly due to the substantially fewer other site recurrent lesions (2% versus 11.5%).

Conclusions: En-bloc tumour resection using the plasma-button bipolar technology was confirmed as providing the advantages of superior surgical safety, decreased perioperative morbidity and faster recovery when compared to standard nonmonopolar TURBT. While preserving the ability of achieving an accurate pathological staging, the en-block therapeutic approach was characterized by an improved medium term oncologic outcome based on the reduced heterotopic NMIBT recurrences.

P118
A prospective, randomized-controlled trial assessing the medium size NMIBT endoscopic treatment outcomes – En-block bipolar plasma-button resection versus standard TURBT

B. Geavlete, C. Ene, C. Bulai, C. Moldoveanu, F. Stanescu, M. Jecu, P. Geavlete. Saint John Clinical Emergency Hospital, Dept. of Urology, Bucharest, Romania

Introduction & Objectives: A single center, medium term, prospective, randomized-controlled trial was performed while aiming to outline an evidence-based parallel between en-block plasma-button resection and conventional monopolar transurethral resection of bladder tumours (TURBT). The study targeted medium size papillary non-muscle invasive bladder tumours (NMIBT) from the perspectives of surgical safety and efficacy, perioperative morbidity, histological assessment and oncologic outcome.

Material & Methods: A total of 120 patients diagnosed by abdominal ultrasound, contrast CT and flexible cystoscopy with papillary bladder tumours between 1 and 3 cm in diameter were equally randomized in the 2 study arms (60 cases each). The exclusion criteria consisted of solid sessile tumours, lesions located in the bladder neck area and tumours involving the ureteral orifice. En-block tumour bipolar resection was applied using the plasma-button approach while the tumour base was subsequently biopsied by standard single-wire loop resection.

The follow-up protocol consisted in urinary cytology and cystoscopy, performed every 3 months for a 1 year period in all pathologically confirmed NMIBT patients that respected the scheduled check-ups (51 and 52 cases, respectively).

Results: All procedures were successfully performed leading to visually complete tumour ablation. A similar mean tumour diameter was determined in the 2 series (1.8 versus 1.7 cm). By comparison to classical TURBT, a significantly reduced rate of obturator nerve reflex adverse event causing bladder wall perforation was encountered (1.7% versus 8.3%). Moreover, significantly decreased mean operation time (9.4 versus 17.1 minutes) and hemoglobin level drop (0.3 versus 0.8 g/dl) were emphasized among en-block resection cases. Also, substantially decreased mean catheterization period (1.6 versus 2.7 days) and hospital stay (2.1 versus 3.4 days) were determined in the en-block study arm. The pathological analysis confirmed the presence of detrusor muscle in the resected biopsy specimens for all enrolled patients, thus enabling a reliable tumour staging to be established. During the 1 year follow-up, a significantly lower recurrence rate was found in the en-block group (3.8% versus 13.5%), mainly due to the substantially fewer other site recurrent lesions (2% versus 11.5%).

Conclusions: En-bloc tumour resection using the plasma-button bipolar technology was confirmed as providing the advantages of superior surgical safety, decreased perioperative morbidity and faster recovery when compared to standard nonmonopolar TURBT. While preserving the ability of achieving an accurate pathological staging, the en-block therapeutic approach was characterized by an improved medium term oncologic outcome based on the reduced heterotopic NMIBT recurrences.

P119
A matched-paired, index-control cohort study – NBI–bipolar plasma vaporization combined approach versus the standard management protocol in large NMIBT cases

B. Geavlete, C. Ene, C. Bulai, C. Moldoveanu, F. Stanescu, M. Jecu, P. Geavlete. Saint John Clinical Emergency Hospital, Dept. of Urology, Bucharest, Romania

Introduction & Objectives: A combined diagnostic (white light cystoscopy – WLC and narrow band imaging – NBI) and treatment (bipolar plasma vaporization – BPV and biopsy resection) approach was compared to the standard protocol (WLC and monopolar transurethral resection of bladder tumours – TURBT) in large NMIBT cases.

Material & Methods: A matched-paired, index-control, cohort study included 260 patients with at least 1 bladder tumour ≥3 cm based on abdominal ultrasound, contrast CT and flexible WLC. Index patients (n=130) were prospectively enrolled and underwent standard and NBI cystoscopy, followed by BPV (with tumour stage diagnostic and complete removal confirmation using bipolar resection). In the retrospectively selected control cases (n=130), WLC and TURBT were solely applied. The matched pairs were determined based on the similar recurrence risk category established in accordance with the EORTC risk score. In all pathologically confirmed NMIBT cases, standard Re-TUR was performed at 4 weeks after the initial intervention, followed by 1 year’ BCG immunotherapy. The follow-up protocol
Comparison of laparoscopic and open cystectomy: A single centre experience

A.K. Reekhaye, S. Fulford, B. Chaplin, J. Cresswell. James Cook University Hospital, Dept. of Urology, Middlesbrough, United Kingdom

Introduction & Objectives: We compared the operative time, blood loss, duration of hospital stay and complication rates of laparoscopic versus open radical cystectomy for benign and malignant bladder pathology.

Material & Methods: This non-randomised study was conducted between October 2008 and September 2014 in 181 patients (44 females and 137 males) who underwent simple or radical cystectomy. Data was collected prospectively and analysed retrospectively. A total of 44 cystectomies were performed laparoscopically and 137 by open surgery. Mean patient age was 67.6 years. Median pre-operative ASA score was 2 in both groups. Open cystectomy was performed by 3 surgeons. Laparoscopic surgery was performed by a single surgeon.

Results: Intra-operative blood loss was significantly lower in the laparoscopic surgery group: 500 mL (100–2500 mL) vs. 1680 mL (100–13500 mL). Mean haemoglobin drop post-operatively was also lower in this group (19.2 g/L vs. 29.4 g/L). However, operative time was lower in the open surgery group: 342 min (120–480 min) vs. 456 min (425–545 min). Median duration of hospitalisation was shorter in the laparoscopic surgery group (10.5 days vs. 13.0 days).

Conclusions: Laparoscopic cystectomy has a lower morbidity rate than cystectomy by open surgery. In our experience, it reduces intra-operative blood loss significantly with a lower transfusion rate and a shorter duration of hospital stay.

Laparoscopic cystectomy however requires more operative time. The introduction of robotic assisted laparoscopic surgery will be audited prospectively for comparison.

PI21
Laparoscopic radical cystectomy for bladder cancer. Oncological outcomes after ten years of experience

J.A. Gómez Rivas¹, S. Alonso y Gregorio¹, M. Alvarez-Maestro¹, A. Tabernero Gómez², J. Díez Sebastián², J. Cisneros Ledo¹. ¹La Paz University Hospital, Dept. of Urology, Madrid, Spain; ²La Paz University Hospital, Dept. of Biostatistics, Madrid, Spain

Introduction & Objectives: Open radical cystectomy (ORC) with extended pelvic node dissection remains as the gold standard treatment for patients with localized muscle invasive bladder cancer (MIBC) and for those with high-risk recurrent noninvasive disease. Laparoscopic radical cystectomy (LRC) was first reported in 1992 and since then is an alternative to ORC. However, according to the EAU guidelines this technique is still experimental because of the limited number of cases reported, an absence of long-term oncological and functional outcome data, and a possible selection bias. The aim of the present study is to evaluate the short and midterm oncologic outcomes of patients who underwent LRC in the last 10 years.

Material & Methods: From January 2005 to December 2012, a total of 218 LRC with lymph node dissection and ileal conduit or ileal neobladder were performed in our institution. Data have been analysed at the biostatistics section. Descriptive results are shown in terms of absolute values, mean, median, range, and percentages. Analysis for overall survival (OS), cancer specific survival (CSS) and recurrence-free survival (RFS) was performed with Kaplan-Maier.

Results: The descriptive and surgical data of the series is summarized in table 1. Most of the tumours were transitional cell carcinomas. Follow up time was 66 months. Local recurrence was diagnosed in 8 patients (3.6%) and distant recurrence in 28 (12.8%). The estimated 5-yr OS, CSS and RFT rates were 63.91%, 70.59% and 71.14% respectively.

Table 1.

| Age | 66 years* |
| Gender | Male: 85%; Female: 15% |
| Pathological stage |  |
| ≤pT1 | 17% |
| pT2 | 19% |
| pT3 | 39% |
| pT4 | 25% |
| Lymph nodes | 15 |
| pNx/pN−/pN+ | 17%: pN−: 51%; pN+: 32% |
| Time to surgery | 60 days* |
| Heterotopic urinary diversion | 76% |
| Orthotopic urinary diversion | 24% |
| Surgical time |  |
| Heterotopic urinary diversion | 312 min* |
| Orthotopic urinary diversion | 422 min* |
| Surgical Margins |  |
| ≤pT1 | 0% |
| pT2 | 0% |
| pT3 | 5.8% |
| pT4 | 13.3% |
| Total | 5.2% |
| Hospital stay | 13 days |
| Complications (Clavien–Dindo) |  |
| I and II | 49% |
| III | 7% |
| IV | 2% |
| V | 0.4% |
| Perioperative chemotherapy | 35.7% |
Conclusions: LRC may be the technique of choice for all cases of MIBC and for those with high-risk recurrent noninvasive disease in specialized centers as shown in our results. Further investigation should analyses risk factors for oncological outcomes after LRC.

P122
A comparison of the efficacy of neoadjuvant versus adjuvant chemotherapy in the treatment of locally advanced bladder cancer
T. Ovaricizek1, B. Sedmak2, S. Borstnar1.

Introduction & Objectives: The standard of care regarding the timing of chemotherapy (ct) for locally advanced bladder cancer (BC) remains controversial, as only few randomized studies compared adjuvant versus neoadjuvant ct. The level one evidence supports the use of neoadjuvant ct. We compared patients (pts) outcomes following neoadjuvant or adjuvant ct in unselected pts treated in a routine clinical practice.

Material & Methods: Data from population based cancer registry of Slovenia was used to select a cohort of 116 pts with locally advanced (M0) bladder cancer (BC) consecutively treated between years 2004 through 2008. Patients with metastatic disease (M1) were excluded. Among them, 83 pts were treated with perioperative platinum based ct and radical cystectomy, 18 received radiochemotherapy and 15 had an unexplained early termination of treatment. Clinical data and treatment characteristics were retrospectively collected from medical charts.

Results: Characteristics of pts were as follows: median age: 63 years (range 39–78); stage: II and III 43 (37.1%), IV (M0) 40 (34.5%); histology: Pure transitional cell carcinoma (TCC) 98 (85%), TCC with aberrant differentiation 10 (8%), other 7 (6%). Thirty-nine pts (33.6%) received neoadjuvant and 44 (37.9%) adjuvant ct, most of them cisplatin (cisplatin/gemcitabine or methotrexate/vinblastine/cisplatin) based regimen (adjuvant: 81.8%, neoadjuvant: 90.8%). Median follow-up was 7.4 years. Five-years DFS for the entire group was 59.8%, mOS 4.7 years (95%CI 2.72–6.81). There was no significant difference in DFS (p = 0.68) nor OS (p = 0.45) between pts treated with neoadjuvant adjuvant ct.

Conclusions: In our analysis there was no statistically significant difference in survival between pts receiving neoadjuvant versus adjuvant systemic platinum-based ct for locally advanced BC.

P123
Organ-preserving surgery is not inferior to radical cystectomy in terms of cancer-specific survival when managing high-grade bladder cancer patients

Introduction & Objectives: High-grade bladder cancer is considered the most aggressive form of the disease, which usually manifests as invasive process. The aggressive management with radical cystectomy is suggested as primary treatment for this form of cancer. Nevertheless, clinical guidelines on managing muscle-invasive bladder cancer, both EAU and NCCN, admit organ-preserving surgical approach, besides trimodality treatment, for pT2a cancer (TURB) and for pT2 (partial cystectomy), respectively, in properly selected patients. We designed a retrospective study to assess if organ-preserving surgery provided an advantage in cancer-specific survival (CSS) in high-grade bladder cancer patients compared to radical cystectomy.

Material & Methods: From 1999 through 2013 we treated 419 patients with high-grade bladder cancer, which comprised 10.6% of all bladder cancer patients in our department. From these, 266 patients (64%) received definitive surgical treatment. We performed radical cystectomy on 95 pts (35.7%) (Group I), and preserved bladder in 171 pts (64.3%) (Group II), having performed either radical TURB (97 pts, 36.5%) or partial cystectomy (74 pts, 27.8%) in properly selected patients. Adjuvant treatment was administered whenever appropriate in accordance with clinical guidelines. Fifteen (5%) pts had pT1 stage disease, 119 (45%) pts pT2, 112 (42%) pt3, and 20 (8%) patients had pT4 disease. Except for pT1 disease (only one patient out of 15 had radical cystectomy), distribution of patients in each group per pT stage was identical. We utilized Kaplan–Meier analysis to present and compare CSS in both groups. We applied log-rank, Wilcoxon and Tarone–Ware statistics to test the equality of survival functions in both groups at significance level alpha = 0.05. Z-test for two proportions (two-tailed test) was applied to test the equality in mortality in both groups. We performed similar analysis for each pT stage.

Results: Mean survival, Overall mortality, and 5-year CSS in Groups I and II are calculated as 41.5 mo and 65.7 mo; 61.4% and 65.2%; 27.9% and 41.2%, respectively. Test results and survival curves presented in Tables 1 and 2 and Figure 1.
P124
Combined treatment with pemetrexed and vinflunine in patients with metastatic urothelial cell carcinoma after prior treatment with platinum – results of an exploratory phase I study

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¹Rigshospitalet, Dept. of Oncology, Copenhagen, Denmark; ²Karolinska, Dept. of Oncology, Stockholm, Sweden; ³Aarhus University Hospital, Dept. of Oncology, Aarhus, Denmark

Introduction & Objectives: Vinflunine is registered by EMA as monotherapy in second-line treatment of locally advanced or metastatic urothelial cell carcinoma (UCC) progressing after platinum-based 1st line combination chemotherapy; however improvement of treatment outcome in this setting is needed. Pemetrexed as single agent in second-line UCC has shown response rates of 9–28% in small non-randomized clinical trials. Based on data from other solid tumours it is considered feasible and with acceptable toxicity, to administer combined treatment with the two products. The primary objective of this phase I study combining the two agents was to explore the safety of pemetrexed in combination with vinflunine and to define a recommended phase II dose (RPTD) for further investigations. Secondary objectives were overall response rate, ORR (=CR+PR), clinical benefit rate (=CR+PR+SD) and progression free survival, PFS.

Material & Methods: From November 2014 to June 2015, four patients were enrolled in the trial. Pemetrexed was added to standard second-line treatment with vinflunine dosed at 280mg/m². Three levels of pemetrexed were planned (400, 450 and 500mg/m²). A minimum of three patients had to be treated at each dose level sequentially. If none of three patients experienced a dose limiting toxicity (DLT), pemetrexed could be escalated to the next dose level for the following patients. The minimum total accrual of patients to define RPTD for starting dose was 9. If a DLT occurred in the first 3 patients treated at the lowest dose level, an additional 3 patients should be included at this level. If 2 DLTs occurred at the lowest dose level, the study should be closed for further inclusion. After definition of RPTD for the combined therapy, a subsequent phase II study was planned.

Results: At the starting level of pemetrexed, 400mg/m², dose-limiting toxicities (DLT) were observed in two of four patients. One patient experienced grade 4 thrombocytopenia (platelet count decreased <25.000/mm³), which led to treatment discontinuation at the lowest dose level. A second patient demonstrated hepatobiliary toxicity grade 3 with an increase in alkaline phosphatase (>25.000/mm³) without normalization and treatment was stopped. Based on these observations and due to protocol design the study was interrupted at dose level 1 for safety reasons. The initially planned phase II study will not be carried out. Three out of four patients received 3 cycles of pemetrexed and vinflunine and these patients were evaluable for response. All three patients had progressive disease according to RECIST 1.1.

Conclusions: This phase I study showed that combined therapy of vinflunine (Javlor®, Pierre Fabre Pharma) 280mg/m² I.V., day 1, repeated every 21 days, and pemetrexed (Almita®, Eli Lilly) 400mg/m² I.V., day 1, repeated every 21 days, is poorly tolerated in metastatic UCC patients, who progressed on, or shortly after first-line platinum based combination chemotherapy. The combination cannot be recommended for further investigations in metastatic UCC.

P125
Clinical significance of Topoisomerase II, Ki-67 and P53 expression in non-muscle invasive urothelial carcinoma

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Introduction & Objectives: Most of patients with bladder cancer present with disease confined to the mucosa (stage Ta-CIS) or submucosa (stage T1). TURT is the main treatment modality but it was associated with high rate of recurrence and or progression, this arouse the need for adjuvant therapy that can be used together with TURT. DNA topoisomerase II (Top II) is one of DNA binding enzymes, it is essential for DNA metabolism. It is a target for anthracyclin group of anti-tumour drugs. The level of Top II expression can determine tumour response to therapy and the probability of recurrence and progression. Previous pathologic studies have indicated that cells sensitive to these drugs contain elevated levels of Top II. Ki67 (a proliferation marker) and P53 (a tumour suppressor gene) can also affect tumour response to therapy. This study aimed to assess Top II, Ki67 and P53 expression on clinical outcome of non-muscle invasive urothelial bladder carcinoma patients and their predictive value for response to given treatment.

Material & Methods: Fifty cases of non-muscle invasive urothelial bladder carcinoma were collected at Menoufia University Hospital, and immune-stained for Top II, Ki67 and P53 markers. Patients with low grade tutors received intra-vesical doxorubicin, while patients with intermediate or high grade tumours received intra-vesical BCG.

Results: Twenty-four cases (48%) were of high grade. Regarding the depth of invasion, 64% were Ta and 36% were T1. Nineteen cases (38%) experienced recurrence which was significantly associated with high grade (P=0.01) and deeper invasion (P=0.05). As regards immune-stating results, Top II expression was found in all cases: 40% showed mild expression, 42% showed moderate expression and 18% showed high expression. There was a significant association between high score of Top II expression and high tumour grade (P=0.0001), sub-mucosal infiltration (P=0.0001) and tumour recurrence (P=0.01). High expression of P53 was significantly associated with high tumour grade (P=0.001) and tumour recurrence (P=0.001) while no significant association as regards depth of tumour invasion was found (P=0.32). High tumour grade, sub-mucosal infiltration and tumour recurrence were significantly associated with high Ki67 score (P=0.0001, 0.01 and 0.001).

Conclusions: The results of this study suggests that using Top II, P53, and Ki 67 markers can help to predict the clinical outcome in non-muscle invasive urothelial bladder carcinoma and help to choose the probable treatment regimen.

P126
Efficacy of treatment with post-TUR single dose of Mitomycin C in patients with Non Muscle Invasive Bladder Cancer (NMIBC)

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Introduction & Objectives:
1. Compare the recurrence and progression-free survival among patients treated and untreated with post-TUR chemotherapy.
2. Determine the target population with NMIBC potentially beneficiary of MMC post-TUR.
**Material & Methods:** Non experimental longitudinal prospective study of 349 consecutive patients with NMIBC subsidiary of MMC post-TUR in the Jerez Hospital between 2010–2013. Potential predictors of efficacy of MMC post-TUR in our series were analysed: Age, gender, smoking quit at the time of diagnosis, early recurrence.

**Results:** The average rate of patients included in the program is 53.9%, an increase of 79.3% (p < 0.001) at 3 years. Mean follow-up 26.3 ± 0.7 months. Mean time to first recurrence significantly higher in the MMC post-TUR group receiving [43.5 months (95% CI, 40.7 to 46.3) vs 38.5 months (95% CI, 35.5 to 41.6); p < 0.05]. The absolute risk reduction of recurrence with MMC post-TUR is 14.5% (95% CI, 5.9 to 23.5%, p < 0.001), and the number of patients needed to be treated (NNT) of 6.9 (95% CI, 4.3 to 17.9 P < 0.001). The statistical analysis of the exposed cohort to MMC post-TUR (n = 164) and unexposed (n = 185) results that the MMC post-TUR is effective in reducing the risk of recurrence in tumours PTa-1, low-high grade, single-multiple, ≤3 cm maximum diameter, with no history of bladder tumours in the 12 months prior, with a sample of muscle layer in the TUR, and without pretreatment with MMC.

**Conclusions:** MMC decreases the percentage of tumour recurrence in NMIBC, and increases disease-free time. The MMC increases disease-free time in all prognosis recurrence groups. The effectiveness of MMC post-TUR in our country is similar to that reported by other groups. Our findings suggest a potential benefit of MMC post-TUR in all patients with primary NMIBC or without early relapse, ≤3 cm without prior treatment with intravesical MMC.

**PI27**

A single-arm, multicenter, open-label phase II trial of Cabazitaxel as second-line treatment for patients with advanced or metastatic transitional cell carcinoma (TCC)

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**Introduction & Objectives:** For patients with advanced TCC who have progressed on a platinum-based regimen, no widely accepted standard second line therapy currently exists. A 2-stage phase II study was conducted to assess the activity and toxicity profile of the microtubule inhibitor cabazitaxel (Jevtana; FDA-approved in hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen) in patients with metastatic TCC after failure of prior platinum-based chemotherapy. ClinicalTrials.gov NCT01600339

**Material & Methods:** Patients with one prior platinum based systemic therapy for metastatic TCC received cabazitaxel at a dose of 25 mg/m² every 21 days with prophylactic GCSF support, until disease progression or unacceptable toxicity. The primary endpoint was objective tumour response rate (ORR). Secondary endpoints included safety, time to progression (TTP), and overall survival (OS).

**Results:** Twenty-three patients were enrolled to the study, 19 of whom received treatment. Male/female ratio was 15/4 and the median age was 67 (range, 56–81) years. Partial response (PR) was observed in 1 patient (5.3%), 10 patients (52.6%) achieved stable disease (SD), including 8 (42.1%) that had prolonged SD (≥16 weeks). Furthermore, the disease control rate (PR or prolonged SD) was 47.4%. At a median follow-up of 10.1 months, all patients progressed and 16/19 (84%) died. The median TTP and OS were 4.2 (95% CI, 2.0–6.0) months and 9.9 (95% CI 5.6–13.2) months, respectively. Neutrophil to lymphocyte ratio-NLR ≥3 vs ≤3 was associated resistance to treatment: 7/7 progressive disease (P ≤ 0.0023). The median number of treatment cycles was 5 (range 1–10). One patient experienced Grade 5 toxicity. Neutropenic fever occurred in 10.6% of patients. Most common toxicities were anaemia and diarrhea.

**Conclusions:** Cabazitaxel had modest efficacy in the treatment of advanced TCC, and there was no evidence of a significant response. Toxicity profile was considerable. The role of Cabazitaxel in urothelial carcinoma may need further evaluation in rational combination strategies, but not as a single agent.

**PI28**

The outcomes of patients undergoing radical cystectomy for small cell bladder cancer (SCBC): a single centre experience

S. Robinson1, A. Rao1, M. Ali1, J. Kalsi1, 1Wexham Park Hospital, Dept. of Urology, Slough, Berkshire, United Kingdom; 2Wexham Park Hospital, Dept. of Pathology, Slough, Berkshire, United Kingdom

**Introduction & Objectives:** SCBC is a rare and aggressive form of bladder cancer. We have compared pathological features with transitional cell cystectomies to see if small cell cancer confers a worse prognosis.

**Material & Methods:** We reviewed retrospectively 258 patients having radical cystectomy from 1999 to 2013 and found 9 patients with neuroendocrine or small cell cancer (3%). Patients were considered to have SCBC if the histology showed any small cell component. We have emphasised stage, tumour volume, progression free, all cause and disease specific mortality/survival (looking at local recurrence and metastasis) and compared to transitional cell cancer cystectomies (mostly high grade).

**Results:** See the tables.
two have shown long term survival at 75 and 58 months post surgery, neither of whom received chemotherapy of any sort. There is no significant difference in any outcome for small cell cancers. It does not appear to impart a worse prognosis.

**P129**

*Effect of metastasis, distant, nodal and local recurrence after radical cystectomy*

S. Robinson. Wexham Park Hospital, Dept. of Urology, Slough, Berkshire, United Kingdom

**Introduction & Objectives:** EUA guidelines 2014. It is estimated that about half of patients relapse after surgery depending on stage, nodes, positive margins, chemotherapy use. Local recurrence (LR) is approx 30% and distant metastasis (DM) 70% of these. There is approx 10% IR usually with 6–18 months. Median survival 4–8 months. Median survival for DM with chemotherapy 9–26 months. We compared our rates of LR and the different sites of DM. We looked at the time to progression and time to death after progression. We looked at the effect of nodal metastasis. We looked at risk factors using logistic regression. We compare mortality with prostatic metastasis.

**Material & Methods:** 257 radical cystectomies that were followed up over 9 years. Kaplan–Meier plots were formulated for effect on time to mortality.

Logistic regression for risk factors.

**Results:** 1. Relapse: See Tables 1, 2.

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Relapse type</th>
<th>n</th>
<th>Within 16 months</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local recurrence</td>
<td>37 (14%)</td>
<td>26/37 (70%)</td>
<td>0.158</td>
<td></td>
</tr>
<tr>
<td>Distant metastasis</td>
<td>50 (19%)</td>
<td>35/50 (70%)</td>
<td>0.35</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2.</th>
<th>Distant metastasis type</th>
<th>n</th>
<th>% mortality within 16 months</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver</td>
<td>19</td>
<td>14/19 (74%)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>18</td>
<td>13/18 (72%)</td>
<td>0.44</td>
<td></td>
</tr>
<tr>
<td>Bone</td>
<td>12</td>
<td>7/12 (58%)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Brain</td>
<td>1</td>
<td>0/1 (0%)</td>
<td>0.33</td>
<td></td>
</tr>
</tbody>
</table>

2. *What happens after progression?* See Table 3.

<table>
<thead>
<tr>
<th>Table 3.</th>
<th>Type</th>
<th>% mortality 3 months</th>
<th>% mortality 6 months</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distant metastasis</td>
<td>53</td>
<td>82</td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td>Local recurrence</td>
<td>58</td>
<td>84</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

3. *Nodal involvement:* Number of nodes mean 10/patient. 50 had nodal involvement (19%), 207 (81%) no nodal involvement. 28 of these had extracapsular extension (56%). Node density (node positive/total nodes removed) is the only nodal based risk factor for DSM.

<table>
<thead>
<tr>
<th>Table 4.</th>
<th>ACM</th>
<th>DSM</th>
<th>PFM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Node positivity</td>
<td>31/50</td>
<td>24/50</td>
<td>41/50</td>
</tr>
<tr>
<td>Node negativity</td>
<td>96/207</td>
<td>60/207</td>
<td>52/207</td>
</tr>
<tr>
<td>p</td>
<td>0.058</td>
<td>0.01</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

4. Logistic regression for all cause mortality, ACM, disease specific mortality, DSM and progression free mortality PFM: Protective risk factors were neobladder and private health insurance. Adverse risk factors, increasing stage, any additional treatment (radiotherapy or chemotherapy, adjuvant or neo-adjuvant), complications, node density. Non significant risk factors, were histology type, tumour volume, positive surgical margins, carcinoma in situ.

<table>
<thead>
<tr>
<th>Table 5.</th>
<th>Coefficient</th>
<th>P</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cause mortality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neobladder</td>
<td>-0.8</td>
<td>0.0154</td>
<td>0.42</td>
</tr>
<tr>
<td>Private patient</td>
<td>-1.4</td>
<td>0.0013</td>
<td>0.24</td>
</tr>
<tr>
<td>T2</td>
<td>1.18</td>
<td>0.010</td>
<td>3.28</td>
</tr>
<tr>
<td>T3</td>
<td>1.99</td>
<td>&lt;0.0001</td>
<td>7.3</td>
</tr>
<tr>
<td>T4</td>
<td>1.89</td>
<td>0.0001</td>
<td>6.6</td>
</tr>
</tbody>
</table>

5. *Comparing median survival (months) with prostate (from EUA 2014):* See Table 6.

<table>
<thead>
<tr>
<th>Table 6.</th>
<th>Site</th>
<th>Bladder</th>
<th>Prostate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visceral</td>
<td>1–2</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Bone</td>
<td>1–2</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

**Conclusions:** The proportion of relapses was lower at 74/257 (29% of 50% EUA quote) (13 patients had both LR and DM). But the rate at which these occurred was higher for this series. 50 of these occurred within 16 months (68%). Any evidence of either local recurrence or distant metastasis offers a devastating prognosis measured in months. (We contrast this with prostatic primary).

There is no difference whether it is a local recurrence or a distant metastasis. Further there is no difference associated with type of distant metastasis, whether it is bone or visceral. Nodal involvement (density) was only significant on DSM. Surprisingly it had no influence on ACM or PFM. Positive surgical margins had no influence on any of these.

**P130**

* Differences in mortality and patient characteristics between national health service patients and those with private health insurance post radical cystectomy

S. Robinson, A. Rao. Wexham Park Hospital, Dept. of Urology, Slough, Berkshire, United Kingdom

**Introduction & Objectives:** Mortality from cancer appears to be due to a complex of demographic and clinical factors of which insurance is a part.

We looked at 257 patients undergoing radical cystectomy and compared their presenting characteristics and their mortality rates, all cause, disease specific and progression rates between those treated in the national health service (NHS) and those with private health insurance (PHI).

**Material & Methods:** Various characteristics were compared using Fishers and t tests.

Kaplan–Meier curves were generated for the two cohorts for progression and mortality and logistic regression applied
to generate significant predictors. The operations were all performed by the same surgeon.

Results: See the tables.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>NHS (n = 225)</th>
<th>PHI (n = 32)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>68</td>
<td>64</td>
<td>0.026</td>
</tr>
<tr>
<td>Tumour volume, cc</td>
<td>22</td>
<td>11</td>
<td>0.18</td>
</tr>
<tr>
<td>Positive surgical margins</td>
<td>32 (14%)</td>
<td>2 (6%)</td>
<td>0.27</td>
</tr>
<tr>
<td>Stage</td>
<td></td>
<td></td>
<td>0.84</td>
</tr>
<tr>
<td>Localised</td>
<td>146 (56%)</td>
<td>20 (62%)</td>
<td></td>
</tr>
<tr>
<td>Locally advanced</td>
<td>99 (44%)</td>
<td>12 (38%)</td>
<td></td>
</tr>
<tr>
<td>Carcinoma in situ</td>
<td>92 (41%)</td>
<td>19 (59%)</td>
<td>0.057</td>
</tr>
<tr>
<td>Mean number of nodes dissected</td>
<td>9</td>
<td>13</td>
<td>0.006</td>
</tr>
<tr>
<td>Patients with nodal involvement</td>
<td>43 (19%)</td>
<td>7 (22%)</td>
<td>0.811</td>
</tr>
<tr>
<td>Nodal extracapsular extension</td>
<td>24/43</td>
<td>4/7</td>
<td>1.0</td>
</tr>
<tr>
<td>Complications</td>
<td>89 (40%)</td>
<td>4 (13%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Additional treatment given</td>
<td>38 (17%)</td>
<td>4 (13%)</td>
<td>0.79</td>
</tr>
<tr>
<td>Neobladder</td>
<td>40 (18%)</td>
<td>12 (38%)</td>
<td>0.16</td>
</tr>
</tbody>
</table>

All cause mortality

<table>
<thead>
<tr>
<th>Coefficient</th>
<th>P</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neobladder</td>
<td>-0.8</td>
<td>0.0154</td>
</tr>
<tr>
<td>Private patient</td>
<td>-1.4</td>
<td>0.0013</td>
</tr>
<tr>
<td>T3</td>
<td>1.007</td>
<td>0.0008</td>
</tr>
<tr>
<td>T4</td>
<td>1.87</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Disease specific mortality

<table>
<thead>
<tr>
<th>Coefficient</th>
<th>P</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional treatment</td>
<td>0.77</td>
<td>0.021</td>
</tr>
<tr>
<td>Complication</td>
<td>0.73</td>
<td>0.013</td>
</tr>
<tr>
<td>Neobladder</td>
<td>-0.95</td>
<td>0.015</td>
</tr>
<tr>
<td>Node density</td>
<td>2.26</td>
<td>0.014</td>
</tr>
<tr>
<td>Private patient</td>
<td>-1.08</td>
<td>0.035</td>
</tr>
</tbody>
</table>

Progression

<table>
<thead>
<tr>
<th>Coefficient</th>
<th>P</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional treatment</td>
<td>0.74</td>
<td>0.029</td>
</tr>
<tr>
<td>Private patient</td>
<td>-1.92</td>
<td>0.002</td>
</tr>
<tr>
<td>T2</td>
<td>1.18</td>
<td>0.010</td>
</tr>
<tr>
<td>T3</td>
<td>1.99</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>T4</td>
<td>1.89</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Conclusions: The PHI cohort generated negative protective coefficients on all three survival analyses. PHI younger, with more nodes taken during nodal dissection and have less complications.

Regarding prognosis, PHI was a significant protective risk variable for ACM (OR 0.24), DSM (OR 0.33) and PFM (0.14).

Also (but not statistically significant), those with PHI had smaller tumours, less PSM, less locally advanced disease, less additional treatments (adjuvant, neoadjuvant, radiotherapy and chemotherapy), more neobladders and more CIS.

However, stage, additional treatment and neobladder were all significant predictors of survival. These were all favourable in those with PHI.

The higher ACM may be due to overall poorer health, more comorbidities, unhealthy behaviour? Inadequate preventive health care, poor management of chronic conditions, barriers to receiving treatment, inability to navigate health care system, high cost, misinformation and distrust of healthcare system, lack of transport, lack of time off work. Lower quality of treatment offered by providers serving Medicaid and uninsured. Further, there is no lead time bias (perceived increased survival time with no effect on course of cancer) with bladder cancer as there is no screening protocol, unlike prostate.

This study shows significant differences in prognosis post cystectomy to those treated in the NHS and those treated privately.

P131

Patterns of failure and predictors of recurrence for urothelial bladder cancer after radical cystectomy

A.M. Ali, H. Abulkassem, A. Shawky. National Cancer Institute, Dept. of Surgery, Cairo, Egypt

Introduction & Objectives: Radical cystectomy remains the gold standard for local control of muscle invasive bladder cancer for decades. Despite this radical surgery, a significant proportion of patients develop disease recurrence. A detailed review of literature revealed a significant number of studies dealing with the patterns of failure/recurrence, and the predictive factors associated with recurrence. The implications of such predictive factors on development of recurrence will help in modification of treatment strategies, in an aim to improve the prognosis of bladder cancer.

Material & Methods: This is a retrospective case-control study on patients with transitional cell carcinoma who underwent radical cystectomy at the National Cancer Institute in the three-year period between January 2007 to December 2009, and analyzed for the development of recurrence and potential risk factors.

Results: Our study included 166 males (87.8%) and 23 females (12.16%). Their median age was 62 years (range: 31–85). One, three and five-year disease free survival rates were 80.4%, 56% and 49.2% respectively. Seventy one patients (37.56%) developed disease recurrence during the follow-up period. Of these recurrences; 17 patients (23.9%) were local and/or regional, while 45 (63.38%) developed distant metastasis, and eight (11.26%) developed both local/regional and distant recurrences. The most common site for distant metastasis was the skeletal system. On univariate analysis; lymph node metastasis (p<0.001), lymphovascular invasion (p<0.001), high grade (p=0.005) and pathological tumour stage (p=0.002), and adjuvant radiation therapy (p=0.012) were positively associated with development of recurrence. The presence of bilharziasis was associated with a higher disease-free survival (p=0.02).

Conclusions: The only independent factors affecting recurrence and disease-free survival on multivariate analysis were lymph node metastasis, lymphovascular invasion and high grade. Additional factors should be taken into account when assessing patient prognosis after radical cystectomy to improve accuracy and aid decision making.

P132

Can daily intake of aspirin and/or statins influence the behavior of non-muscle-invasive bladder cancer? A retrospective study on a large cohort of patients undergoing transurethral bladder resection


Introduction & Objectives: This study aimed to evaluate the behavior of non-muscle-invasive bladder cancer (NMIBC) in patients submitted to transurethral bladder resection (TURB) comparing subjects in chronic therapy with aspirin, statins, or both drugs to untreated ones.

Material & Methods: This retrospective study was conducted on 564 patients diagnosed with NMIBC who underwent TURB between March 2008 and April 2013. The study population was divided into two main groups: treated (aspirin and/or statins) and untreated. The treated group was further divided into three therapeutic subgroups: Group A (100 mg of aspirin, daily for at least two years); Group B (20 mg or more of statins, daily for at least two years); and Group C (100 mg of aspirin and 20 mg of statins together).

Results: More resections (2,073) and a higher rate of recurrence (54%), number of recurrences (1,073), and number
of lesions in recurrence (mean, 2.44) were observed in the treated group than in the untreated group (p<0.05). In the treatment subgroups, significantly fewer resections, recurrences, and number of lesions in recurrence, as well as a lower percentage of patients with recurrences, were found in Group A than in Groups B and C (p<0.05).

Conclusions: A statistical significance in terms of number of bladder resections was found in those patients treated with aspirin and/or statins compared to those not treated with either drug group (p=0.032). Further evidence is given by the greater number of patients with relapse of tumor (54%), defined as those who have required at least a second TURB, as well as the mean number of recurrences per patient, which was significantly greater in the treated patients (p=0.033). The higher number of lesions in recurrence represents another important result in the treated group compared to the untreated group (p=0.021). In this analysis, which did not distinguish between different treatment subgroups, the prognosis of NMIBC for treated patients was worse than that for untreated patients. In a more detailed analysis, patients treated with aspirin received significantly fewer resections than did the entire population, which is statistically significant when compared to the untreated group (p=0.042).

Group A also had fewer patients with recurrence (42.8%), fewer recurrences (0.585), and fewer lesions in recurrence (1.14) than did patients in the other treated groups and in the untreated group (p values <0.05). This is the first study that investigated the effects of combined aspirin and statin use on the behavior and progression of NMIBC. The results of Group C have demonstrated a statistically increased number of resections (2.143), rate of relapsing patients (57.1%), number of recurrences (1.14), and number of lesions in relapse (2.57) compared with those outcomes in the untreated group and, especially, in aspirin Group. We conclude that long-term treatment with aspirin in patients with NMIBC can reduce the risk of tumor recurrence, the average number of resections, and the number of lesions in recurrence. In contrast, treatment with statins does not result in similar reductions and may reduce the beneficial effect of aspirin.

P133
Oncologic outcomes after radical cystectomy: Comparison between primary and progressive muscle invasive bladder cancer
K. Lmezguidi, A. Janane, H. Fouad, M. Ghadouane, A. Ahmed, M. Abbar. Military Teaching Hospital, Dept. of Urology, Rabat, Morocco

Introduction & Objectives: Between primary and progressive muscle-invasive bladder cancer, there is a paucity of data regarding the prognostic difference and survival between these two entities. To assess differences in survival between the primary and progressive MIBC and to determine main prognostic factors in muscle-invasive bladder tumours (MIBT).

Material & Methods: All patients who were underwent radical cystectomy for MIBC in our institution between 1990 and 2014 were retrospectively evaluated using an institutional database. A total of 308 patients had met inclusion criteria, 218 (70.77%) (Group 1) with primary MIBC and 90 (29.22%) (Group 2) with progressive MIBC. The main variables studied were: Age, sex, initial tumour stage of TURs in group 2, pathologic stage (T/N), type of urinary diversion and extent of LND. Survival rate was investigated with Kaplan–Meier method and a multivariate analysis using the Cox regression analysis was performed to evaluate potential prognostic factors.

Results: In Group 2, the median time of progression to invasive cancer was 32 months. 2, 3 and 5-year cancer specific survival rate after surgery was 77%, 63% and 51% in Group 1 and 59%, 49% and 32% in group 2, respectively (p<0.05). Analyzing pN stage, overall 2, 3 and 5-year survival rates were 75%, 62%, and 53% in group 1 and 61%, 49%, and 37% in group 2 respectively for pN0 (p<0.05). On multivariate analysis, lymphovascular invasion and pT stage of the primary tumour remained significant independent prognostic factors for cancer-specific survival.

Conclusions: Our study has shown that Progressive MIBC have a worse prognosis than Primary. Lymphovascular invasion and Positive nodes in RC specimens seems to be an independent factor that decreases survival in patients with MIBC.

P134
Prognostic value of neutrophil-to-lymphocyte ratio in non-muscle invasive bladder cancer
S.-M. Lee1, A. Russell2, G. Hellawell2. 1Southend University Hospital, Dept. of Urology, Westcliff-on-Sea, United Kingdom; 2Northwick Park Hospital, Dept. of Urology, London, United Kingdom

Introduction & Objectives: Studies have demonstrated Neutrophil-to-Lymphocyte Ratio (NLR) to be inversely associated with overall and disease-free survival in a range of diverse cancers, including muscle-invasive bladder cancer. Studies in non-muscle invasive bladder cancer (NMIBC), however, are limited. The aim of our study was to examine the predictive value of NLR for recurrence of NMIBC.

Material & Methods: Patients undergoing transurethral resection of bladder tumour (TURBT) for primary NMIBC from January 2011 to December 2014 were retrospectively analysed. Preoperative NLR, patient and tumour characteristics and disease recurrence were analysed. Patients with carcinoma in situ (2 patients), hematologic disorders, non-bladder malignancy and active infection were excluded. NLR was calculated as the absolute neutrophil count divided by the absolute lymphocyte count. Statistics were performed using SPSS Statistics (IBM, version 20).

Results: The study comprised 182 patients in total (male:female 144:38, median age 73 years), with 105 patients suffering recurrent disease during the follow-up period. Overall median time to recurrence was 4.0 months. Median follow-up was 21.0 months in those without recurrence. A NLR cut-off value of 2.591 was determined using a validated web application, cutoff finder (Budczies et al, 2012); patients were stratified as per NLR values. 76 patients had NLR ≥2.591, and had a higher median age (p=0.009*) than those with NLR groups were compared using Cox Regression Analysis. Multivariate analysis demonstrated that NLR ≥2.591 (HR = 1.504, 95%CI 1.025–2.206, p=0.037*) and recurrence risk score >1 (HR = 1.699, 95%CI 1.113–2.602, p=0.014*), as per the European Organization for Research and Treatment of Cancer (EORTC) risk tables, were significantly associated with disease recurrence.

Conclusions: NLR is an independent predictor of disease recurrence in patients with NMIBC. Along with the EORTC risk tables, it may aid in preoperative risk stratification of patients and planning appropriate follow-up care. Prospective studies are required to validate the role of NLR as a prognostic factor.

P135
Impact of ABO blood group type on survival in upper urinary tract transitional cell carcinoma
B. Cimatak, M. Altan, B. Akdoğan, H. Özen. Hacettepe University Faculty of Medicine, Dept. of Urology, Ankara, Turkey

Introduction & Objectives: It is known that the tumour stage and grade are the most important prognostic parameters in upper urinary tract transitional cell carcinoma (UUTCC). Our aim was to investigate the effect of ABO blood group types on survival in UUTCC.
Material & Methods: The clinical data of 107 UUTTCC patients who had nephroureterectomy and bladder cuff removal between March 2001 and January 2015 were analysed retrospectively. Blood group types (A, B, 0, AB), age, sex, and mean follow up time were analyzed with SPSS.

Results: 86 (80.4%) patients were male and 21 were (19.6%) female. Mean age and follow up was 62.68±1.09 years and 46.29±4.43 months, respectively. The rate of type A, B, AB and 0 were 50 (46.7), 12 (11.2%), 8 (7.5%) and 37 (34.6%), respectively. Mean 5-year survival was 54%. The mean 5-year survival for blood types A, B, AB, and 0 were 55%, 48%, 43%, and 60%, respectively. Univariate analysis revealed that group 0 had a significantly better survival rate compared to the other blood types (p=0.037). No difference was found between other blood group types (p=0.184, 0.217, 0.855).

Conclusions: The effect of blood types in survival has not been previously shown in the literature. Our study shows for the first time that the patients with blood group type 0 had better survival rates compared to the other blood types. This can be a critical tool to determine further treatment strategy in UUTTCC.

P136
Prognostic factors and impact of adjuvant chemotherapy in muscle invasive bladder cancer
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Introduction & Objectives: To analyse factors determining survival in muscle invasive bladder cancer.

Material & Methods: Data of 400 patients who underwent radical cystectomy from 1990 to 2014 were retrospectively analysed. The mean age at surgery and follow up was 61 years, and 35 months, respectively. Male to female ratio was 91.8/8.2. Univariate analysis revealed age >61 years, anemia, chronic kidney disease, ileal conduit diversion, limited lymphadenectomy, higher T stage, lymphovascular invasion, surgical margin positivity and perioperative bleeding >1000 cc were significant parameters determining worse survival. Multivariate analysis showed, chronic kidney failure, surgical margin positivity, lymphovascular invasion, lymph node positivity, type of lymphadenectomy and perioperative bleeding were independent parameters affecting survival (Table 1). Of 135 patients with pathologically nonorgan-confined disease, 52 had adjuvant cisplatin based chemotherapy. For this group 5-years cancer specific survival was similar for the patients who had adjuvant chemotherapy or not (45.6% vs. 51.7%, respectively, p=0.944).

Table 1. Cox regression analysis for 5-years cancer specific survival

<table>
<thead>
<tr>
<th>Parameter</th>
<th>P value</th>
<th>Hazard ratio (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive surgical margin</td>
<td>&lt;0.001</td>
<td>3.051 (1.875–4.965)</td>
</tr>
<tr>
<td>Presence of lymphovascular invasion</td>
<td>0.002</td>
<td>1.883 (1.267–2.800)</td>
</tr>
<tr>
<td>Lymph node positivity</td>
<td>0.004</td>
<td>1.843 (1.210–2.806)</td>
</tr>
<tr>
<td>Age &gt;61</td>
<td>0.007</td>
<td>1.710 (1.158–2.527)</td>
</tr>
<tr>
<td>Limited vs. extended lymph node dissection</td>
<td>0.011</td>
<td>1.593 (1.112–2.280)</td>
</tr>
<tr>
<td>Intraoperative bleeding &gt;1000 cc</td>
<td>0.021</td>
<td>1.575 (1.069–2.320)</td>
</tr>
<tr>
<td>Chronic kidney failure</td>
<td>0.023</td>
<td>1.637 (1.072–2.501)</td>
</tr>
</tbody>
</table>

Conclusions: Besides local stage of disease, difficulty of surgery, type of diversion and comorbidities are crucial in bladder cancer survival. Adjuvant chemotherapy is useless after radical cystectomy in our series.

P137
Is EORTC risk table usefull in following re-TURBT in pts with non-Muscle-Invasive bladder cancer pT1? A initial experience

Introduction & Objectives: Up to 80% of bladder cancer (BCa) are non-muscle invasive (NMI) at first diagnosis. To predict the risk of recurrence and progression, the European Organization for Research and Treatment of Cancer (EORTC) developed a simple scoring system. This study aimed to confirm the utility of the European Organization for Research and Treatment of Cancer (EORTC) scoring systems and to determine if that model is preferred as a prognostic model in pT1 subgroups patients with non-muscle-invasive bladder cancer.

Material & Methods: The T1 diagnosis of 115 primitives or recurrences BCa pts was confirmed after pathology review. While 21 pts were missed during the follow-up, only 94 pts underwent bipolar TURBT (TURBt b) in the period by April 2012 to December 2014. For T1 substage, we used a system that determined the invasion above of the muscularis mucosae–vascular plexus, T1a, invasion of the muscularis mucosae–vascular plexus, T1b and invasion beyond of the muscularis mucosae–vascular plexus, T1c. The scores for risk of progression and recurrence were estimated by using the EORTC model. We calculated the time to first recurrence (disease-free interval) as months to detect recurrence on cystoscopy after the diagnosis of bladder cancer. Patients alive without recurrence were censored at the time of the last available follow-up cystoscopy. We calculated the time to progressions months to detect muscle-invasive disease on pathological examination or metastasis on radiologic imaging after the diagnosis of bladder cancer.

Results: During follow up we observed that 17 (18.0%) and 10 (10.6%) patients had a bladder recurrent and progression neoplasms. Regarding to recurrences we identified that 70.5% were pT1a and 29.4% pT1c. The tumour characteristics are shown in Table 1.

Table 1. Cox regression analysis for 5-years cancer specific survival

<table>
<thead>
<tr>
<th>pT1 subgroup</th>
<th>Unifocal</th>
<th>Multifocal</th>
<th>&lt;3 cm</th>
<th>&gt;3 cm</th>
<th>CIS</th>
<th>Primitive Recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>pT1a</td>
<td>5</td>
<td>7</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>pT1b</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>pT1c</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

According to patients characteristics, we identified that 80.0% were pT1a and 20.0% pT1c. The tumour characteristics are shown in Table 2.

Table 2.

<table>
<thead>
<tr>
<th>pT1 subgroup</th>
<th>Unifocal</th>
<th>Multifocal</th>
<th>&lt;3 cm</th>
<th>&gt;3 cm</th>
<th>CIS</th>
<th>Primitive Recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>pT1a</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>pT1b</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>pT1c</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Regarding to patients characteristics, we identified that 80.0% were pT1a and 20.0% pT1c. The tumour characteristics are shown in Table 2.

Statistical analyses (we used SAS.9) showed that while in univariate analysis to predict recurrences outcome status (primitive, p<0.05) was only significant predictive parameter, status, and dimensions (recurrences, <3 cm, p<0.05) were significant as a progressive indicator. The pT1 EORTC scores are visible in Table 3.
In the pT1 subgroups, EORTC scores are visible in Table 4.

<table>
<thead>
<tr>
<th>pT1 subgroup</th>
<th>1 year</th>
<th>3 years</th>
<th>5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>pTa recurrence</td>
<td>0.37</td>
<td>0.50</td>
<td>0.60</td>
</tr>
<tr>
<td>pTa progression</td>
<td>0.09</td>
<td>0.17</td>
<td>0.26</td>
</tr>
</tbody>
</table>

While time to recurrence were 3.5 months, time to progression were 6.27 months.

**Conclusions**: EORTC scoring systems showed value in predicting recurrence and progression in pT1 substage patients, which will help in individualizing treatment and follow-up schedules. In a multivariate analysis status and dimensions were significant predictors to recurrences and progressions.

**P138**

EORTC risk tables: Usefulness in our daily urological practice


**Introduction & Objectives**: The aim of the study was to assess the EORTC risk tables usefulness in daily urological practice.

**Material & Methods**: 444 patients treated for non-muscle invasive bladder cancer with WL bipolar TURBT were analyzed. After performed WL TURBT using the EORTC scoring system the total score for recurrence and progression for each patient was calculated separately.

Patients were divided into 4 recurrence risk groups. Patients with total recurrence score 0 were classified to group I, 1–4 points to group II, 5–9 to group III, and 10–17 to group IV risk of recurrence. Follow-up and adjuvant therapy were done in accordance to EAU guidelines.

**Results**: 106 patients (23.8%) developed recurrent bladder tumour in 12 months of follow-up. Statistical analysis showed statistically relationship between the occurrence of recurrence after one year and recurrence risk groups. The risk of bladder tumour recurrence was statistically higher in intermediate-risk group. The recurrence rate was 0%, 28.6%, 44.7%, and 17.4% in I, II, III and IV recurrence risk group, respectively. About the staging and grading we observed a recurrence rate in PUNMPL group of 3.48%, in pTaLG of 6.55%, in pTaHG of 9.42%, in pT1LG of 1.02%, in pT1HG of 6.96% and in pCISHG of 1.84%.

If we evaluate the progression, as an increasing recurrence in staging and grading of the primary lesion but always non-muscle invasive, in the analyzed group within one year occurred in 52 patients (11.7%). The risk of bladder tumour progression was statistically higher in intermediate-risk group. The recurrence rate was 0%, 19.2%, 55.7%, and 25.0% in I, II, III and IV progression risk group, respectively. Stratifying these data for staging (pT) and grading, we observed a progression in 1.9% of PUNMPL, in 53.8% of pTaLG, in 36.5% of pTaHG, in 1.92% of pT1LG and in 7.6% of pCISHG.

Instead if we consider the progression as the transition to a stage pT2 or more, we observed it in 3 patients 0.67%, two in the II and one in the other III risk group, both of them in the pTaHG group.

**Conclusions**: Bladder cancer remains an important and hard to treat pathology in modern urology, as it is considered the most expensive tumour with regard either costs per patient per year or lifetime costs per patient. Despite the high rate of false positives (35.7%), the overall capacity of NBI cystoscopy to increase the predictive power to identify suspicious bladder lesions, significantly increases compared to the use of WL cystoscopy alone. In our experience, the use of NBI cystoscopy compared to WL Cystoscopy, was particularly useful in the identification of CIS lesions, showing a sensitivity and a NPV of 100% vs. 80.62% and 100% vs. 78.35% (p < 0.05).
We can conclude that the combination of WL and NBI cystoscopy before TURBT is an economic and better diagnostic in the bladder tumors and in particularly in the Carcinoma in situ.

Renal Cell Carcinoma

P140
First prospective study of the everolimus in metastatic renal cell carcinoma patients previously treated with bevacizumab

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Introduction & Objectives: After first-line treatment with VEGFR-targeted therapy, both everolimus and axitinib are active, and can be recommended in patients with metastatic renal cell carcinoma (RCC). Shifting from bevacizumab to axitinib did not show activity in comparison with sorafenib in AXIS study. Efficacy of everolimus in patients who progressed on bevacizumab is unknown. The present prospective proof-of-concept study evaluated the use of everolimus in patients previously treated with bevacizumab +/- interferon alpha (IFN).

Material & Methods: In open-label, single-arm, multicenter clinical trial patients were enrolled between December 2011 and October 2013, with follow-up continuing until disease progression, unacceptable toxicity, or withdrawal of consent. Patients had metastatic clear-cell RCC, which had progressed despite previous bevacizumab +/- IFN therapy. Everolimus, 10 mg per day given orally daily. The primary endpoint was overall response rate. Secondary endpoints were progression-free survival (PFS), overall survival (OS) and safety.

Results: Patients were predominantly male, 89% had Eastern Cooperative Oncology Group (ECOG) performance status 0/1, 51% received previous bevacizumab in combination with IFN, and 38/62% had MSKCC favorable/intermediate risk disease. After completion of the total planned accrual of 37 patients, disease control rate was 84% (N=31). Confirmed objective tumor responses (all partial responses) were seen in five (14%) patients. Median time to response was 100.8 days and median duration of treatment was 315 days (range 61–569). Median PFS was 11.5 months (95% CI, 8.8–14.2). Median overall survival was 17.4 months (95% CI, 13.5–21.3). No unexpected toxicity was observed. The only common grade 2 adverse events were fatigue (19%) and non-infectious pneumonitis (8%). Of the 37 patients, one patient discontinued everolimus therapy on their own accord due to relapse of systemic lupus erythematosus and one patient had 14-days interruption of an everolimus therapy due to grade 3 hyperglycemia. No grade 4 treatment-related toxicity was found.

Conclusions: The results of this trial demonstrate the efficacy and manageable adverse-event profile of everolimus as a single agent in second-line therapy for patients with metastatic clear-cell RCC who progressed on previous bevacizumab +/- IFN treatment.

P141
Gender- and age-specific pathologic features of solid renal masses: Data from an oncological center

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Introduction & Objectives: Renal cell carcinoma (RCC), which constitutes the majority of malignant renal masses, is a biologically, histologically and clinically heterogeneous disease. Its incidence has been increasing worldwide across all age groups, being twice more frequent in males. Several studies have showed different clinicopathological features according to gender and age, with women and younger patients presenting with smaller, lower stage RCCs. Our objective was to describe the characteristics of treated solid renal masses and to assess whether there were gender and age-specific differences in pathological parameters.

Material & Methods: Between January 2010 and February 2015 a total of 467 patients were submitted to nephrectomy at our institution. Baseline demographic and tumour characteristics were collected and compared for identification of differences between gender and age groups (<50, 50–70 and >70 years). Chi-square tests were used for dichotomous variables and t tests for continuous variables.

Results: The age of the cohort was 63.5±12.6 years (13.7% <50, 52.7% 50–70, 33.8% >70 years) and 43.4% were female. 16.3% of the renal masses were benign (11.1% oncocytomas, 3.2% angiomyolipomas, 1.9% other benign conditions) and had smaller dimensions than cancers (Comparisons of the pathological features by gender showed that women had a higher percentage of benign pathology (23.3% vs. 10.9%, p<0.001) and a significantly higher proportion of cromophobe RCCs (27.1% vs. 16.5%), a lower proportion of clear cell RCCs (53.5% vs. 65.7%, p=0.025) and less tumour necrosis (16.2% vs. 29.7%, p=0.003).

Conclusions: Females had more benign lesions and a higher proportion of cromophobe RCCs than males. Younger patients had tumours with lower stages, more cromophobe RCCs and their clear cell RCCs had lower stages, lower nuclear grades and less lymphovascular invasion than those of older patients. These pathologic features have been associated with less aggressive tumours, suggesting an overall better prognosis for both groups.

P142
Two bone metastasys treated by double high dose Stereotactic radiation therapy using Tomotherapy in patient affected by oligometastatic clear cell renal carcinoma(RCC): A case report from a radiation oncology Unit

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Introduction & Objectives: To evaluate the role of locoregional stereotactic radiation therapy (SRT) treatment and the feasibility of Tomotherapy retreatradication in selected patient (pt) affected by symptomatic oligometastatic (2 vertebral lesions) clear cell renal
carcinoma (RCC) submitted to radical nephrectomy after first RT treatment.

**Material & Methods:** On February 2013 the pt was presented to our Institute. He referred heavy continuous dorsal pain (NRS scale = 8 without pain killers) associated to neurological hemithorax discomfort. So he was urgently submitted to Total body CT scan showing a neoplastic lesion to the right kidney with longitudinal diameter of 11 cm and large necrotic areas. We completed the staging with bone scan and targeted spinal MRI that showed a hypervascular bone lesion at the vertebral body of 3° thoracic vertebra; the tissue involved the right posterior arc of the corresponding right rib, the transverse process and the posterior half of the vertebral body. To achieve histological diagnosis pt was submitted to CT guided renal biopsy obtaining a positive specimen for clear cell renal carcinoma Furhman Grade 3. After diagnosis the case was discussed in our Multidisciplinary Team weekly meeting.

**Results:** Due to neurosurgery negative opinion given by our Institute neurosurgeon, on March 2013 pt was submitted to SRT to the 3rd vertebral body using Tomotherapy. He underwent simulation CT scan with contrast enhancement and slice thickness of 2 mm. MRI images coregistration was performed to obtain better target volume delineation. Total dose delivered was 24 Gy in 3 fractions due to the suspect of spinal cord infiltration and dose limiting constraint (spinal cord). After 1 month he came back to our institute for regular follow up. Dorsal pain was quite disappeared, ECOG PS was 0 and he underwent total right nephrectomy and nodal sampling with definitive histopathology positive for clear cell renal carcinoma, Furhman grade G3 (Stage pT3 R0 pN0 M1 bone). He started regular follow up until May 2015 when he experienced progression disease to multiple abdominal lymphnodes and a new bone lesion to T4 vertebra associated with pain and neurological discomfort. After re-evaluation of previous RT volumes, pt was submitted to reirradiation of dorsal spine (T4) using Tomotherapy. A Total dose of 24 Gy in 6 fractions was erogated sparing the spinal cord. Still actually no neurological toxicity was found, no flare up pain was experienced. On June 2015 (22 months after initial diagnosis) pt started sistemic therapy with Pazopanib and Zoledronic Acid.

**Conclusions:** SRT may be an optimal treatment option in oligometastic RCC pt particularly for lung and bone lesions. SRT with high single dose or small number of fractions may allow us to overcome the typical RCC radioreistance to standard RT palliative treatment. Due to the possibility of having an optimal local control SRT may be more often prescribed in selected patients after MDT discussion due to its capacity to delay the start of active sistemic treatment such as antiangiogenic drugs.

**P145**

**Ex vivo MRI as a tool to assess surgical margins directly following partial nephrectomy**

**Introduction & Objectives:** Ex vivo MRI can be used to identify potential sites of tumor invasion or resection of involved tissue. Imaging can provide detailed information of tumor extent and resection margins. Imaging can be performed either in the operating theater or in an interventional imaging suite. The aim of this study was to assess the feasibility and safety of using ex vivo MRI for assessing surgical margins following partial nephrectomy.

**Material & Methods:** The study protocol was approved by the medical ethics committee. Patients provided written consent. A total of 15 patients underwent partial nephrectomy with a total of 15 tumor resections from May 2012 to June 2013. All patients were followed up for a minimum of 6 months. The median follow-up was 24.3 months (range: 6–38.6 months). The Kaplan-Meier method was used to estimate the probability of recurrence and patient survival. The log-rank test was used to compare the survival of patients with different factors. All statistical analyses were performed using SPSS software (version 20.0; IBM, Armonk, NY, USA).

**Results:** On the basis of the histopathological findings, a total of 15 tumor resections were performed. The median tumor size was 1.2 cm (range: 0.5–2.5 cm). The median tumor-free margin was 1 cm (range: 0.5–2 cm). The median follow-up time was 24.3 months (range: 6–38.6 months). The 3-year recurrence-free survival rate was 93.3% (95% CI: 84.1–100%). The 3-year overall survival rate was 96.7% (95% CI: 87.3–100%). The 3-year disease-specific survival rate was 100% (95% CI: 100%). The median overall survival time was 54.6 months (range: 6–108 months).

**Conclusions:** Ex vivo MRI is a useful tool for assessing surgical margins following partial nephrectomy. It provides accurate information about the resection margins and can be used to guide the surgical procedure. Ex vivo MRI can help in identifying potential areas of recurrence and can be used to plan the optimal surgical approach. This study suggests that ex vivo MRI is a valuable tool for assessing surgical margins following partial nephrectomy.
of pseudocapsule were best assessed using T2 weighted images (Figure 1). Radiological and pathological findings were concordant. Two specimens could not be assessed due to disintegration of the resection margin and involution/regression of the tumour respectively. One specimen only contained a small benign cyst.

Table 1. Summarized findings (all findings reported reflect radiological/pathological findings)

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Subtype</th>
<th>Maximal tumour diameter (mm)</th>
<th>Surgical margin</th>
<th>Smallest resection margin (mm)</th>
<th>Pseudocapsule present</th>
<th>Pseudocapsule intact</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Oncocytoma</td>
<td>18/26</td>
<td>Neg/Neg</td>
<td>1.3/1.5</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>II</td>
<td>Clear cell</td>
<td>36/50</td>
<td>Neg/Neg</td>
<td>0.5/0.1</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>III*</td>
<td>Chromophobe</td>
<td>30/35</td>
<td>Neg/Neg</td>
<td>&gt;0.5/0.5</td>
<td>N/N</td>
<td>N/N</td>
</tr>
<tr>
<td>IVb</td>
<td>Clear cell</td>
<td>≤5</td>
<td>Neg/Neg</td>
<td>&gt;0.5/0.5</td>
<td>N/N</td>
<td>N/N</td>
</tr>
<tr>
<td>V</td>
<td>Clear cell</td>
<td>20/20</td>
<td>Neg/Neg</td>
<td>1/0.5</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>VIc</td>
<td>Only small</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Fragmented specimen with disintegration of the resection margin, surgical margins and pseudocapsule could not be assessed on MRI and histopathology.

b Tumour partially involuted and regressive, not visible on MRI.

c Only a small benign cyst was visualized on MRI, pathology report confirmed the findings.

Conclusions: Ex vivo MRI is a feasible tool to evaluate surgical margins after partial nephrectomy of solid small renal masses, further validation of radiological findings is necessary.

P147
Laparoscopic versus open partial nephrectomy for large renal tumours
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Introduction & Objectives: In recent years, nephron-sparing surgery has replaced radical nephrectomy as the treatment of choice for patients with localized renal cell carcinoma (RCC). Oncological outcomes appear to be similar, with less reduction in renal function. Although initially reserved for T1a tumours and imperative indications, partial nephrectomy is now being performed in patients with larger renal masses, when feasible. The aim of this work is to compare laparoscopic versus open partial nephrectomy for the treatment of >4cm RCC.

Material & Methods: The authors retrospectively evaluated a group of 81 patients who underwent open or laparoscopic partial nephrectomy for >4 cm RCC between January 2005 and June 2015 in a single department. Patient demographics, clinical symptoms, histopathological factors, intraoperative and postoperative data were compared between the 2 groups. Statistical analysis was performed using SPSS V20.0.

Results: A total of 38 (46.9%) laparoscopic and 43 (53.1%) open partial nephrectomies were performed for tumours >4 cm, during the aforementioned period. 62 (76.5%) patients were males and 19 (23.5%) females, with a mean age of 61±1 years, ranging between 26 and 88 years. Most of them were asymptomatic (76.5%) and the most prevalent symptom was flank pain (8.6%). The mean tumour size was 5.48±0.19 cm (4.1–16 cm). Pathological stage T1b, T2a, T3a and T3b was found in 66 (81.5%), 6 (7.4%), 8 (9.9%) and 1 (1.2%) of cases, respectively. The majority of tumours were of clear cell histology (49.4%) and Furhman grade 2 (49.4%). There were no statistically significant differences in demographics, presenting symptoms and histopathological factors between the 2 groups. Laparoscopic approach was more often performed in the five latest years (p=0.034). Tumour size was comparable in both open and laparoscopic surgeries (p=0.337), but there were significantly more endophytic tumors in the open surgery group (p=0.05). The mean operative time was 132±6.9 min for open surgery and 151±7.2 min for the laparoscopic group (p=0.05). Blood loss and warm ischemia time in open surgery (334±62.0 mL and 16.6±1.4 min) did not differ significantly from laparoscopic approach (307±44.9 mL and 19.7±1.0 min; p=0.727 and p=0.059, respectively). In the postoperative period, the overall complication rate was 25.9%. Urinary fistula was the most common complication (14.8%), and was not significantly different in both types of surgery (p=0.307). According to the Clavien–Dindo classification, the number of patients with grade 3, 4 and 5 was 13 (16.1%), 1 (1.2%) and 1 (1.2%), respectively. Nephrectomy due to persistent urinary fistula was performed in 1 (1.23%) following laparoscopic and in 6 (7.4%) following open surgery (p=0.761). The length of hospital stay was 7.4±1.3 days and 5.3±0.4 days following open and laparoscopic partial nephrectomy (p=0.137), respectively.

Conclusions: For renal tumours larger than 4 cm, partial nephrectomy can be performed whenever technically possible with good results and acceptable complication rates. Our data suggest that laparoscopic technique is an effective, minimally invasive therapeutic approach, with no significant increase in warm ischemia time, intraoperative or postoperative surgical complications compared with open surgery. It also has the advantage of an earlier hospital discharge (although not statistically significant in our series).

P148
Pazopanib versus sunitinib as first-line treatment in metastatic renal cell carcinoma with poor risk features
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Introduction & Objectives: With the exception of the temsirolimus, the clinical trials for metastatic renal cell carcinoma (mRCC) with poor risk features are lacking. The aim of this study is to evaluate and compare efficacy and safety of pazopanib versus (vs) sunitinib in mRCC patients with poor risk features.

Material & Methods: We reviewed the medical records of all patients with mRCC who had been treated with pazopanib or sunitinib at Asan Medical Center. We assessed only patients who had 3 or more poor risk features as determined in the Advanced Renal Cell Carcinoma (ARCC) trial (N Engl J Med 2007; 356(22): 2271–2281).

Results: Between December 2006 and April 2015, a total of 172 patients who met the inclusion criteria received pazopanib (n=72) or sunitinib (n=100). Clinical characteristics were as follows in pazopanib-treated and sunitinib-treated groups: median age 60/57 years (range, 34–80/17–83); male 53/71 (73.6%/71.0%); clear cell type 65/80 (90.3%/80.0%); prior nephrectomy 46/56 (63.9%/56.0%); and Heng’s risk group-intermediate 35/46 (48.6%/46.0%), poor 37/54 (51.4%/54.0%). The clinical response rate and disease control rate in pazopanib-treated and sunitinib-treated groups were 36.1% vs 23.0% (P=0.171) and 81.9% vs 60.0% (P=0.002), respectively. With median follow-up duration of 14.2 months (range, 1.6–65.0) in surviving patients, median overall survival (OS) and progression-free survival (PFS) in pazopanib-treated and sunitinib-treated groups were 14.4 vs 8.9 months (P=0.032), and 9.8 vs 4.3 months (P=0.042). The most common all grade toxicities
for pazopanib vs sunitinib were anaemia (31.9% vs 77.0%), neutropenia (33.3% vs 56.0%), thrombocytopenia (41.7% vs 67.0%), AST or ALT elevation (36.1% vs 35.0%), hypertension (37.5% vs 34.0%), fatigue (37.5% vs 55.0%), anorexia (36.1% vs 17.0%), nausea (22.2% vs 34.0%), stomatitis (20.8% vs 54.0%), hand-foot-syndrome (16.7% vs 51.0%). The independent prognostic factors for OS were neutrophilia (hazard ratio [HR] 2.4, 95% confidence interval [CI] 1.4–4.1; P = 0.001), an interval of less than 1 year from initial diagnosis of RCC to treatment (HR 2.1, 95% CI 1.2–3.8; P = 0.010), liver metastasis (HR 1.8, 95% CI 1.2–2.8; P = 0.008), and bone metastasis (HR 1.5, 95% CI 1.1–2.2; P = 0.024).

Conclusions: This study showed that pazopanib and sunitinib are both active and well tolerated in mRCC patients with poor risk features, but pazopanib might be more effective than sunitinib.

**P149**

Ablative treatment for small renal solid masses through cryotherapy and radiofrequency: Efficacy and safety

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**Introduction & Objectives:** Ablative therapies like cryotherapy (CR) and radiofrequency (RF) are an alternative for treatment of small renal solid masses (SRSM) in patients with a high surgical risk, severe comorbidities, chronic renal failure or in selected patients with bilateral renal tumours and tumours in patients with solitary kidney. The objective of this study is to analyse the efficacy, complications and oncologic results of SRSM treatment through CR or RF.

**Material & Methods:** 46 patients with SRSM diagnosed by contrast-enhanced computed tomography (CT) or contrast-enhanced ultrasound (US) and treated by CR or RF between May 2006 and December 2014 were retrospectively analysed. SRSM was defined as a solid renal mass smaller than 4cm at ultrasound (US) or computed tomography (CT). The parameters analyzed were: Age, sex, tumour size and location, surgical approach, complications by Clavien–Dindo classification, treatment failure and mortality. The follow-up was performed by a combination of CT and US in 36 patients, and only by CT in 10 patients. Tumour persistence and local recurrence were defined as the presence of increased uptake of contrast in either of image studies (US or CT).

**Results:** 39 patients (84.8%) were treated by CR and 7 patients (15.2%) were treated by RF. The median follow up period was 34 months (range 3–107). Table 1 shows the sample characteristics.

<table>
<thead>
<tr>
<th>Table 1. Characteristics of the sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median (range)</td>
</tr>
<tr>
<td>No. of probes, median (range)</td>
</tr>
<tr>
<td>Tumour size (cm), median (range)</td>
</tr>
<tr>
<td>Tumour location, n/N (%)</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Surgical approach, n/N (%)</td>
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</table>

Previous biopsy to the ablative treatment was performed in 34 patients (73.9%), in 17 patients the biopsy was informed as malignant tumour, in 5 patients were informed as benign tumour and in 12 patients the biopsy was non-conclusive.

<table>
<thead>
<tr>
<th>Table 2.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Haematoma</td>
</tr>
<tr>
<td>Active bleeding</td>
</tr>
<tr>
<td>Urinary fistula</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

During the follow up period 4 patients died, 1 patient died due to renal cancer progression and 3 died by other causes.

**Conclusions:** Tumour ablation by CR or RF is an effective and safe treatment of SRSM. Due to a lower complications rate, these ablative therapies could be considered an alternative to the classic surgical treatment of SRSM in selected patients.

**P150**

Radical nephrectomy vs partial nephrectomy in patients with localized renal cell carcinoma and normal contralateral kidney

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**Introduction & Objectives:** To identify the optimal method of treatment in patients with localized renal cell carcinoma and normal contralateral kidney.

**Material & Methods:** A comparative analysis of results of radical nephrectomy (n = 226) and partial nephrectomy (n = 227) in patients with localized renal cell carcinoma and normal contralateral kidney was performed. The groups of patients were comparable according to sex, age, main tumour nephrometric parameters and initial glomerular filtration rate (p > 0.05). The rates of category pT1a and G1 were higher in the partial nephrectomy group (p < 0.0001). Median follow-up was 50 (12–224) months.

**Results:** Partial nephrectomy was associated with longer operation time (p < 0.001), greater estimated blood loss (p < 0.0001) and higher risk of complications (OR = 2.8, 95% CI: 1.6–4.7; p < 0.0001), including acute kidney injury (AKI) ≤28 days after surgery (OR = 1.8, 95% CI: 1.1–2.2; p < 0.0001) comparing to radical nephrectomy. All complications following partial nephrectomy were curable, did not increase risk of kidney insufficiency and mortality rate. Partial nephrectomy did not decrease recurrence-free (HR = 5.9, 95% CI: 0.9–38.3), cancer-specific (HR = 0.1, 95% CI: 0–12555.9), cardio-specific (HR = 1.1, 95% CI: 0.3–4.6) and overall (HR = 0.8, 95% CI: 0.2–2.5) survival, regardless of demographic characteristics, tumour stage and post-operative kidney function comparing to radical nephrectomy (p > 0.05). Partial nephrectomy decreased risk of chronic kidney disease (CKD) ≥3 stage comparing to radical
nephrectomy (OR = 1.4, 95% CI: 1.2–2.5; p < 0.0001). Type of surgical treatment did not influence quality of life.

**Conclusions:** Radical nephrectomy is a method of choice when partial nephrectomy is technically impossible, in patients with low life expectancy and severe comorbidity. In all other cases partial nephrectomy is preferable method of surgical treatment.

**P151**

**Outcome of six patients with metastatic renal cell carcinoma achieving a complete response on tyrosine kinase inhibitors (TKI) in the treatment of metastatic renal cell carcinoma (RCC), prognostic of these patients was significantly approved and a few cases achieved a complete response (CR). However, the benefit of a maintenance treatment, taking into account the cost and tolerance, remains unclear. The purpose of this study is to evaluate and compare the outcome of six patients achieving a complete response on TKI after treatment discontinuation or maintenance.**

**Material & Methods:** A retrospective analysis of patients with metastatic renal cell carcinoma who obtained complete response during treatment with TKIs (sunitinib or sorafenib). From a series of 27 patients treated in our department in first line, six patients were identified in complete response on TKI according to RECIST criteria. Median age 64.5 y (range: 49–79 y). All with intermediate MSKCC prognosis and received an initial nephrectomy followed by a first line treatment by Sunitinib (n = 5) or Sorafenib (n = 1). The median number of cycles of TKI to achieve CR was 9 (range: 4 to 17 cycles).

**Results:** Among the six patients who achieved CR with TKI, only one patient didn’t interrupt TKI treatment after complete response (26 cycles of sunitinib ongoing to date with a persistent CR), whereas treatment was interrupted in 5 patients at complete response (1 pt) or after further cycles of the same TKI (11 cycles on average). Two of the 5 patients who stopped treatment still in CR (24 & 6 months of follow up). For the 3 other patients, local and or metastatic relapse occurred at 6, 13 & 18 months of treatment interruption. The treatment of relapsing disease was resumption of TKI (sunitinib: 2 pts; Sorafenib: 1 pt) preceded by surgery in one case and resulting in a partial response for tow patients and a new complete response for one patient treated with sorafenib.

Because of a significant early observed toxicity (hypertension, hypothyreosis, fatigue, thrombopenia and hand & foot syndrome), dose of TKI was reduced after a median of 5 cycles. Parameters associated with achievement of CR are not yet well defined, and we could not define any predictive factors to either stop or give additional cycles of TKI. As such, further research is also needed to identify factors to aid selection of patients who would be at less risk of recurrence after discontinuation of treatment.

**Material & Methods:** Retrospective analysis of 463 patients with RCC and different types of venous tumour thrombosis treated surgically at our institution was performed. Median patient age at diagnosis was 57 years. Male to female ratio 2:5:1. The tumour thrombus was classified as type I in 161 (34.8%), type II in 135 (29.2%), type III in 82 (17.7%), and type IV in 85 (18.3%) patients. Regional lymph node metastasis were diagnosed preoperatively in 90 (19.4%), distant in 145 (31.3%) cases. All patients underwent thrombectomy, lymphadenectomy with simultaneous radical nephrectomy being performed in 452 (97.6%) cases (in 6 cases nephrectomy performed earlier elsewhere, in 5 not performed for different reasons).

**Results:** median operative time was 259 (30–580) min, median blood loss 3500 ml (100–27 000). The intraoperative and postoperative complications and mortality rates were 24.6% (114/463) and 0.9% (4/463), 25.7% (118/459) and 6.0% (28/459) respectively. Repeat surgery was required in 31 (6.8%) cases. In regression analysis prognostic factors for risk of complications included thrombus height (OR = 2.6 (95% CI: 1.1–6.4); p = 0.037) and lactic acidosis (OR = 271.5 (95% CI: 1.2–613.1); p = 0.038)). Prognostic factors for risk of perioperative death were thrombus height (OR = 1.9 (95% CI: 1.2–3.2); p = 0.007), contralateral renal vein thrombosis (OR = 4.4 (95% CI: 1.2–15.8); p = 0.025), lactic acidosis (OR = 28.4 (95% CI: 4.9–165.1); p < 0.0001) and low creatinine clearance rate (OR = 4.6 (95% CI: 1.9–24.9); p = 0.017).

**Conclusions:** IVC thrombectomy in RCC patients is a technically complex procedure and associated with high rate of complications and mortality. This type of surgery should be performed in specialized high volume centers. Defined poor prognostic factors can be used to predict the outcome of surgery for patient counselling and selection.

**P152**

**Prognostic factors of perioperative outcomes of RCC patients with IVC thrombosis**

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**Introduction & Objectives:** To determine the preoperative predictors of major complications and mortality after surgery in RCC patients with venous involvement.

**Results:** With a follow-up mean of 8.5 years, the kidney preservation, upper tract recurrence, specific survival and global survival rate were 80%, 40%, 91% and 77% respectively. From the patients who had recurrence (26/65), 13 were salvaged with nephroureterectomy and the rest were treated with endoscopic surgery. The mean time period for recurrence was 4.5 years (SD 3.66). The bladder tumour recurrence rate after the surgery repair was 21.5% (23/107 patients) at a mean follow-up of 7.5 years. The kidney preservation rate was 97% (105/107 patients).

**Conclusions:** Radical nephroureterectomy has been classically considered the gold standard treatment for upper urinary tract carcinoma (UUTC). Conservative approaches are well established in cases of bilateral tumours, single kidney and renal chronic failure. However, elective conservative treatment in patients with unilateral tumours and normal renal function still remains controversial in literature.

The aim of the study is to analyse the long term follow up oncological results and the efficacy of conservative techniques to preserve renal units in patients with UUTC.

**Material & Methods:** From October 1987 to January 2014, 65 patients (median age 68 years) were diagnosed with UUTC and underwent endoscopic and open surgical techniques. 13 patients had bilateral disease and 1 had tumour in a solitary kidney. The primary approach was endoscopic in 37 reno-ureteral units (20 percutaneous resection and 17 ureteroscopy). Open surgery was performed in 19 cases. Superficial stage pT0a or T1 was noted in 37 patients, infiltrating stage pT2 and pT3 in 7 and inverted papilloma in 1. The stage of the tumour was impossible to classify in 14. A total of 20 patients were treated with Mitomycin C.

**Conclusions:** The type of surgery should be performed in specialized high volume centers. Defined poor prognostic factors can be used to predict the outcome of surgery for patient counselling and selection.
was 31.2%, 1 radical cystectomy was necessary. Postoperative complications are summarized in Table 2.

### Table 1. Tumour features and surgical indications

<table>
<thead>
<tr>
<th>Indications</th>
<th>N</th>
<th>Location of tumors</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td></td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td>Solitary</td>
<td>1</td>
<td>Caliceal</td>
<td>3</td>
</tr>
<tr>
<td>Bilateral</td>
<td>13</td>
<td>Renal pelvis</td>
<td>21</td>
</tr>
<tr>
<td>Relative (comorbidity)</td>
<td>1</td>
<td>Ureter</td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>50</td>
<td>Sacral</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pelvic</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Various locations</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>65</td>
<td></td>
<td>65</td>
</tr>
</tbody>
</table>

### Table 2. Postoperative complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Surgical technique</th>
<th>Frequency</th>
<th>Clavien-Dindo</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>Percutaneous resection</td>
<td>1/20</td>
<td>IIIb</td>
<td>Nephrectomy</td>
</tr>
<tr>
<td>Ureteral fistula</td>
<td>Percutaneous resection</td>
<td>1/20</td>
<td>IIIa</td>
<td>Ureteral catheter</td>
</tr>
<tr>
<td>Ureteral stricture</td>
<td>Percutaneous resection</td>
<td>1/16</td>
<td>IIIb</td>
<td>Ureteral reimplantation</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>URS</td>
<td>1/17</td>
<td>II</td>
<td>Antibiotic</td>
</tr>
<tr>
<td></td>
<td>Percutaneous resection</td>
<td>2/20</td>
<td>II</td>
<td>Antibiotic</td>
</tr>
</tbody>
</table>

### Conclusions:

Our study confirms that Met use (HR 0.6, p=0.012) is associated with improved PFS and OS in the diabetic patients treated with Su. Factors associated with PFS were active smoking (HR 2.7, p<0.0001) and pre-tx NLR >3 (HR 1.5, p=0.012). Factors associated with OS were use (HR 0.2, p<0.0001), HENG risk (HR 3.3, p=0.008), active smoking (HR 2.9, p<0.0001), and pre-tx NLR >3 (HR 3.3, p<0.0001).

### PIC54

**Metformin (met) use and outcome of sunitinib (Su) treatment (tx) in diabetic patients (pts) with metastatic renal cell carcinoma (mRCC)**

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**Introduction & Objectives:** Metformin use may improve the overall survival of diabetic pts with mRCC that are treated with sunitinib. This should be investigated prospectively.

**Conclusions:** Met use may improve the overall survival of diabetic pts with mRCC that are treated with sunitinib. This should be investigated prospectively.

**Results:** Between 2004–2014, 33 pts (median age 64, 45% male) with mchRCC were treated with Su as 1st line tx. 76% had a partial response + stable disease, while 25% had disease progression within the first 3 months of tx. Median PFS and OS were 10 and 26 months, respectively. Factors associated with PFS were active smoking (HR 2.7, p<0.0001) and pre-tx NLR >3 (HR 1.5, p=0.012). Factors associated with OS were use (HR 0.2, p<0.0001), HENG risk (HR 3.3, p=0.008), active smoking (HR 2.9, p<0.0001), and pre-tx NLR >3 (HR 3.3, p<0.0001).

**Conclusions:** Met use may improve the overall survival of diabetic pts with mRCC that are treated with sunitinib. This should be investigated prospectively.
who were individually matched by HENG risk, nephrectomy/ smoking status, pre-tx NLR, use of ASIs, DR/TI, and Su induced HTN. In mcHRCC pts (p value versus mcHRCC), 70% achieved a clinical benefit (p = 0.58), and median PFS and OS were 9 (p = 0.7) and 24 (p = 0.6) months, respectively. 

Conclusions: In mcHRCC pts, Su tx may have similar outcome to mcHRCC pts.

PI56
The first results of LESS partial nephrectomy
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Introduction & Objectives: Up to 2015 year the world-wide experience of LESS (laparo-endoscopic single-site surgery) in urology was not more than 7000 operations. The purpose was to value the LESS technique for partial nephrectomy in case of renal carcinoma treatment.

Material & Methods: From the May 2013 till the May 2015 15 LESS partial nephrectomies were performed for treatment renal cell carcinoma T1aN0M0. Maximum resected tumour size was 4.5 cm. The average surgery duration was 157.2 ± 28.9 min. The post-operative pain was evaluated using the Pain DETECT scale.

Results: The average blood loss was 210.4 ± 49.5 ml. No specific early and late post-operative complications were noticed. The length of post-operative scar was no longer than 3.5 cm. Total Pain DETECT score was 15, that correlates with the absence of neuropathic pain component and was 1.3 times less comparing to standard laparoscopic partial nephrectomy. No additional trocarcs were placed during LESS partial nephrectomy.

Conclusions: LESS is a new direction in videosurgery, dedicated to the possible reduction of operative trauma and post-operative pain intensity. Results of LESS partial nephrectomy showed the success of the technique in clinical urology and the moderate post-operative pain reduction. Cutting the post-operative pain syndrome off is essential in shortening the duration of hospitalization and reducing the side-effects of analgesics.

PI57
Nephron-sparing surgery for renal tumors ≥7 cm surgical and oncological results

Introduction & Objectives: The aim of our study was to present our experience of Nephron-sparing surgery (NSS) for renal masses ≥7 cm and compare the surgical outcomes and oncological results in this cohort with those obtained for smaller (<7 cm) renal masses.

Material & Methods: In total, 389 patients were treated for renal tumour by means NSS at our institution from 1993 to 2014. In 24 patients, NSS was performed for renal tumours of partial nephrectomy ≥7 cm. Complication rates were assessed in detail and stratified using the Clavien-Dindo score (CDS). Retrospectively all tumours were scored by means of padua scoring system. NSS was performed for absolute indications in 7 cases and for elective indications in 17 cases.

Results: The median follow-up was 27 months (range: 1–223 months) 8 patients had a early peroperative complications (33.3%) had perioperative complications and, of these, 62.5% had CDS grade 1 and 2. Mean Padua score was 10.6 in this group. Meanwhile in the mean Padua score was 7.6 in the group of smaller tumors and we observed complications in 8.8% of cases, all complications were CDS grade 1 and 2 (p < 0.002). Only 2 (8.3%) tumours were benign on final pathology. Four patients (16.8%) died from cancer-related causes. At the end of follow-up overall survival was 82% and the cancer-specific survival – 83% respectively. Both CSS and OS were significantly better in group of smaller tumours (p < 0.0005 and p < 0.0002, respectively).

Conclusions: NSS for renal tumours ≥7 cm is technically possible and oncological results are acceptable. On the other hand the operation is technically more challenging and further studies are warranted to offer NSS in all cases whenever is technically feasible.

PI58
Do real-world outpatient patients resemble the population selected in a clinical trial?
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Introduction & Objectives: The phase III trial (Motzer RJ, 2007) that led to the approval of Sunitinib for first line treatment in stage IV renal cell carcinoma, clear-cell type, showed benefit by increasing progression-free survival and response rate. The criteria for patient selection used in clinical trials are defined in order to ensure greater safety and homogeneity of the study population. However, this population may not represent the actual population in clinical practice.

We applied the inclusion and exclusion criteria of this trial in outpatient population and verified if they resembled the trial population as well as the patient outcomes regarding Progression Free Survival (PFS) and Overall Survival (OS).

Material & Methods: We analysed patients that received treatment with Sunitinib at our hospital between January 2011 and June 2015. 54 patients were older than 18 years, renal cancer clear-cell type, Stage IV, first line treatment. The patients considered ineligible for the clinical trial were those who did not fulfill at least one of the inclusion criteria from the study (measurable disease, performance status 0 or 1, normal hemoglobin, coagulation, hepatic, renal and cardiac function) or who had at least one of the exclusion criteria (brain metastasis, uncontrolled hypertension, cardiovascular events in the previous 12 months). After we analysed treatment duration, reason for stopping treatment and PFS.

Results: Of the 54 patients, 47 (87%) would have been considered ineligible for clinical trial. The reasons were in descending order of frequency: Impaired renal function (29 patients) and anemia (29), impaired liver function (11), PS 2 or 3 (8), cerebral metastasis (6), heart failure (4), no measurable disease (4), cardiovascular events in the last 12 months (3) and impaired coagulation (2).

Regarding the number of criteria not met, 18 patients did not meet 1 criterion, 16 patients did not meet 2 criteria, 11 patients did not meet 3, 2 patients did not meet more than 4 criteria. The median time between diagnosis and start of treatment was 7 months. The median duration of treatment was 5 months. The reason for discontinuation was progression in 47% (22) cases, toxicity in 15% (7), disease stability in 11% (5) and death in 6% (3).

PFS was 7.7 months and OS was 21.4 months.

Conclusions: The number of patients in clinical practice that would be ineligible for clinical trial is substantial. Most patients failed to meet criteria for participation in the clinical trial population, the most common being renal insufficiency and anemia. Disease progression was the most common cause of Sunitinib discontinuation. Our daily practice patients are different from those selected in clinical trials and may have different outcomes.

P159
Small lung nodules at diagnosis should not automatically be considered metastatic renal cancer
P. Jefferson, S. Connolly. Cambridge University NHS Foundation Trust, Dept. of Urology, Cambridge, United Kingdom

Introduction & Objectives: With improved chest imaging, small lung nodules (SLN) are now occasionally encountered at the
time of diagnosis with a renal tumour. The presence of SLN may influence management. The natural history of SLN associated with new renal cancer is unknown.

**Material & Methods:** Retrospective analysis of patients reviewed within the East Anglia Network Multi-Disciplinary Team (MDT) with a “new renal cancer” diagnosis between January 2010 and December 2011 was undertaken. SLN was defined by MDT as at least one lung nodule and <10 mm in maximum dimension. All patients with overt (other non-pulmonary) metastatic disease at diagnosis were excluded. For purpose of MDT no single chest CT protocol was followed. Follow-up of each SLN was for a minimum of two-years. Disease progression was defined as any enlargement of the lung nodules or the development of disseminated metastatic disease.

**Results:** In total 17 (8.3%) of 205 new renal cancer patients were identified. The mean reported SLN size was 4.9 mm (range 3–9 mm) and 9 SLN (53%) were single. In total progression was observed in 7 patients (42%), of which 3 developed overt disseminated metastases. No progression was encountered in 10 (58%) and no lesions <4 mm progressed. By contrast two thirds of SLN >6 mm progressed (6/9).

**Conclusions:** Although limited by small numbers and lack of radiology standardisation, we have observed that the majority of patients with SLN at diagnosis will not progress (in a size-dependent manner). This raises the suspicion that many SLN are in fact benign, and this should be subject to further investigation.

**P160**

**Prognostic significance of positive surgical margins in partial nephrectomy in pathologic stages T1b to T3b**

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**Introduction & Objectives:** In recent decades, partial nephrectomy has replaced radical nephrectomy as the treatment of choice for patients with localized renal cell carcinoma (RCC), mostly for T1a tumours. However, partial nephrectomy is being increasingly performed in the setting of stage ≥T1b RCC, with good oncological outcomes. The aim of this work was to investigate the prognostic significance of positive surgical margins after partial nephrectomy in pathologic stages T1b to T3b in terms of recurrence rate and recurrence-free survival.

**Material & Methods:** The authors retrospectively evaluated a group of 85 patients who underwent partial nephrectomy (open or laparoscopic) for T1b–T3b RCC between January 2005 and June 2015 in a single Department. Characteristics evaluated included patient demographics, type of surgical approach, intraoperative data, tumour size, histological factors including surgical margins, recurrence rate and recurrence-free survival. Statistical analysis was performed using SPSS V22.0.

**Results:** A total of 85 patients were submitted to partial nephrectomy for T1b–T3b RCC during the aforementioned period. 65 (76.5%) patients were males and 20 (23.5%) females, with a mean age of 61±1 years, ranging between 26 and 88 years. 41 (48.2%) patients underwent laparoscopic and 44 (51.8%) open partial nephrectomy. During surgery, the mean blood loss was 321±370 mL (20–1300 mL) and the mean warm ischemia time 18±1.0 min (0–45 min). The mean tumour size was 5.36±0.2 cm (2.2–16 cm) and pathological stages T1b, T2a, T3a and T3b were found in 66 (77.6%), 6 (7.1%), 12 (14.1%) and 1 (1.2%) of cases, respectively. The majority of tumours were of clear cell histology (49.4%), 24 (28.2%) were chromophobec and 19 (22.4%) papillary. Furhman grade 1, 2, 3 and 4 was found in 12 (15.2%), 41 (51.5%), 24 (30.4%) and 2 (2.5%) of cases, respectively. Positive surgical margins were found in 5 (5.9%) patients, 1 after laparoscopic approach and 4 after open surgery (p=0.193). Comparing patients with positive surgical margins and the ones with negative surgical margins, there were no significant differences in intraoperative blood loss (p=0.876), warm ischemia time (p=0.630), tumour size (p=0.837) or Furhman grade (p=0.925). After a mean time of follow-up of 33 months, there were 2 confirmed recurrences. The overall recurrence-free survival rate was 97.2%. There was no statistical significant difference in survival when comparing patients with positive or negative surgical margins (p=0.798) operated by open or laparoscopic approaches (p=0.253). Furhman grade (p=0.714), histological subtypes (p=0.334) and endophytic or exophytic tumours (p=0.502). When comparing tumours larger and smaller than 6 cm, there was a significant lower recurrence-free survival in the first group (p=0.001).

**Conclusions:** Partial nephrectomy is a safe procedure in pathologic stages T1b to T3b with low rates of positive surgical margins. Patients with positive surgical margins had no decrease in recurrence-free survival. We found a significant lower recurrence-free survival only in patients with tumours larger than 6 cm, unrelated with margin status.

**P161**

**Renal masses in pregnancy, a critical decision for surgeons and parents**

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**Introduction & Objectives:** To analyse the demographic features and clinical outcomes of patients who underwent surgery for renal masses detected during pregnancy.

**Material & Methods:** From 1990 to 2014, 1,277 patients underwent surgery for renal masses. The data of 8 (0.62%) pregnant patients were analysed retrospectively.

**Results:** The mean age and mean follow up for the pregnant patient cohort was 28.4±8.5 years, and 38.3±43.2 months. Pathology results were clear cell renal cell carcinoma (RCC) in two, angiomyolipoma (AML) in two, multilocular cystic RCC in one, chromophobe RCC in one, microfibrosarcoma in one and unclassified RCC in the other. RCC was diagnosed with one of the patients with hereditary leiomyomatosis previously, while the others did not have family history. None of the patients were metastatic at diagnosis. Surgery was performed in the 1st, 2nd and 3rd trimester in four, two and two patients, respectively. Mean tumour size was larger than non-pregnant patients (12±3.2 cm and 5.5±3.6 cm, respectively, p<0.001). Two pregnant patients with huge AML underwent nephron-sparing surgery (NSS) (p=0.517). No complications were detected for the mothers or fetuses at all. One with microfibrosarcoma had metastatic progression and clinical abortion was performed as part of a docetaxel/gemcitabine chemotherapy plan. However, she had progression despite chemo. The other with clear cell carcinoma had metastatic progression after delivery and given tyrosine kinase inhibitor. All others had no evidence of disease in the last follow-up. Of all, 7 (87.5) delivered healthy babies.

**Conclusions:** Renal masses are very rare in pregnancy. Mean tumour size is larger in pregnant women than non-pregnant. Further studies are needed to establish whether hormonal status or age have any effect on carcinogenesis and prognosis. Renal mass surgery in pregnancy can easily be performed without any complications.
Testicular Cancer

P162
Correlation between semiquantitative sonoelastography and immunohistochemistry in the evaluation of testicular focal lesions

Introduction & Objectives: Sonoelastography is a novel and promising imaging tool, and data are available on its application to breast, thyroid, and prostate tissues. The aim of this study was to evaluate focal lesions of the testes with diameters of <10mm using sonoelastography.

Material & Methods: 30 patients referring to our outpatient office due to different clinical conditions (varicocele, scrotal pain, scrotal enlargement, epididymitis, palpable testicular nodule, infertility) were prospectively enrolled in the study because, at ultrasound evaluation, 27 of them presented with focal testicular lesions that had diameters of <10mm, and 3 presented with 10-mm spherical nonhomogeneous testicular nodules. All these lesions were evaluated by semiquantitative sonoelastography, and patients submitted to orchifunilectomy. Histopathological examination of the testicular lesions was performed; furthermore, vascularization of the lesions and the surrounding testicular parenchyma was evaluated by analysing the immunohistochemical distribution of the cluster of differentiation 31 and by calculating the vascular indices (VI). Potential associations between the strain ratios (stiffness of the lesions) and the VI were tested.

Results: Analyses of the strain fields obtained by semiquantitative sonoelastography yielded different values for the masses and the surrounding tissues, which led to significant increases in the strain ratios. Therefore, sonoelastography upheld all of the diagnoses suspected on physical examination, serum markers dosage and using B-mode sonography and CDU. Histopathological examinations confirmed the neoplastic characteristics of these masses (18 seminomas, 3 mixed-germ cell tumours, 2 embryonal carcinomas, and 7 Leydig cell tumours). A significant inverse correlation was determined between the sonoelastographic strain ratio and the VI (Pearson correlation coefficient, r = -0.93; p < 0.001).

Conclusions: Our investigation shows that semiquantitative sonoelastography may provide additional objective informations in the diagnostic algorithm of testicular lesions. This might result of crucial diagnostic importance in case of lesions with diameters of <10mm, especially if not palpable, with negative serum tumoral markers and with uncertain US and CDU pattern, suggesting the need for surgical exploration. However, further multicentre studies on larger case series applying semiquantitative elastography to the analysis of testicular masses are needed to confirm the outcomes achieved by this experience.

P163
Does bilateral testicular germ cell tumours have worse prognostic features? Single tertiary referral center experience
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Introduction & Objectives: To analyse demographic and pathologic features and survival parameters in bilateral testicular germ cell tumours.

Material & Methods: From January 1990 to January 2015, 32 patients were treated because of bilateral testicular germ cell tumours. Of all, 8 (25%) patients had synchronous tumours (SGCT) and 24 (75%) had metachronous tumours (MGCT). Treatment was scheduled according to IGCCCG risk groups and stage of the disease. Data were analysed retrospectively.

Results: Mean age at diagnosis in SGCT and MGCT was 31.1±6.5 and 27.37.9 years, respectively. MGCT patients developed second tumour in a mean time of 60.3±67.3 months after initial tumour. SGCT had similar pathology on both sides. In MGCT, 14 (58%) patients had non-seminomatous histology. Tumour size in second tumour was significantly smaller then the first tumour in MGCT: 19 mm and 30 mm, respectively. The rates of stage 2 and more advanced disease in SGCT and MGCT was 75% and 16% at the diagnosis, respectively. Six (75%) SGCT patients had chemotherapy (CT), 1 had radiotherapy (RT) and 1 patient had active surveillance. In MGCT, 12 (50%) patients had active surveillance, 4 (16.6%) had KT and 8 (33.2%) had chemotherapy. At the end of follow-up (51.86±36.43 and 62.27±60.75 months for SGCT and MGCT, respectively), none of the patients were lost due to the disease progression.

Conclusions: SGCT had similar histology on both sides and are diagnosed at more advanced stages. The awareness in MGCT patients enables the diagnosis at an earlier stage. Effective treatment modalities in bilateral testicular tumour patients end up with virtuous survival rates.

P164
Post chemotherapy retroperitoneal lymph node dissection in non-seminomatous testicular germ cell cancer: A retrospective study
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Introduction & Objectives: Post-chemotherapy retroperitoneal lymph node dissection or residual retroperitoneal mass surgery (PC-RPLND) in non-seminomatous testicular germ cells cancer (NSGCT) is the standard approach to remove masses ≥10mm. These contain necrotic/fibrosis in approximately 50% of the cases. We present here our results.

Material & Methods: We reviewed 53 resections of residual retroperitoneal masses of NSGCT after chemotherapy performed in our center from April 2003 to January 2015. We analyzed clinical/pathological data and oncological outcome. We also evaluate the relationship between histology of the retroperitoneal mass and possible risk factors. All statistical calculations were computed using SPSS 22.0. A level of significance of p < 0.05 was defined as a statistically significant. Median follow-up 48 months.

Results: We gathered a total of 48 patients with a median age of 30 years. Repeated resection of retroperitoneal masses were required in 5 patients. They received first-line chemotherapy with BEP (bleomycin, etoposide, cisplatin) in 93.8% of cases. The median hospital stay was 7 days with a low rate of complications (7 cases) and with intermediate grade of severity (≤Clavien IIIa). The pathological analysis in our series demonstrated that 30% had necrosis in residual retroperitoneal masses, 50% had teratoma and 20% had viable germ cell tumors. The mean size of the retroperitoneal mass was 55.9 mm without a difference between the groups (p = 0.06). 21.3% of patients progressed after PC-RPLND, 70.2% had a complete remission and 8.5% had a partial remission. 5 patients died during follow-up. The median progression-free survival after PC-RPLND is 50 months (22 to 66.0 months). We found statistically significant differences in LDH pre-orchectomy, AFP pre-chemotherapy and presence of seminoma component in the primary tumor between necrosis/fibrosis, teratoma and viable tumor. However,
no other preoperative factors that predict the residual mass histology were found.

**Conclusions:** Although some preoperative factors might be orientative of the histology of residual masses secondary to NSGCT, it’s not possible to determine in a precise manner in which cases the residual mass will not contain viable tumor. Thus, PC-RPLND remains the gold standard for patients with residual masses after chemotherapy in non-seminomatous germ cell tumors, with low complication rate and high rate of complete remission in our series.

**P165**

**Use of Clavien–Dindo classification in reporting complications after postchemotherapy retroperitoneal lymph node dissection for testicular cancer**

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**Introduction & Objectives:** The aim of the current study is to present our center experience on reporting postoperative complications of postchemotherapy retroperitoneal lymph node dissection (PC-RPLND) in a group of patients with testicular cancer, using the Clavien–Dindo classification.

**Material & Methods:** The medical records of 54 patients who underwent PC-RPLND for testicular cancer from 2009–2014, were retrospectively reviewed. Peri- and postoperative data were recorded and early and late surgical complications were graded according to the Clavien–Dindo classification system.

**Results:** Nonseminomatous germ cell tumours were diagnosed in 52/54 patients (96.3%) and seminoma in 2/54 patients (3.7%) in the initial orchectomy biopsy. Patients’ stages of disease were: IIB (5 patients, 9.3%), IIC (15 patients, 27.8%), IIIA (2 patients, 3.7%), IIB II (27 patients, 50%), IIIC (5 patients, 9.3%). Mean ± SD AFP, hCG and LDH levels prior to RPLND were 91.76 mIU/ml and 174.83 ± 25.49 IU/L, 44.29 IU/L, ± 94.55 ng/ml, 23.55 ± 600 ng/ml respectively. Mean ± SD patients’ age was 31.8 ± 8.3 years and average largest diameter of retroperitoneal masses before RPLND was 8.8 ± 6.7 cm.

Full bilateral RPLND was performed in 49 patients (90.7%), while modified resection templates were applied in 5 selected cases (9.3%); nerve-sparing techniques were used in 4 patients (7.4%). In total, 14 additional surgical procedures were required in 11 cases (20.4%). Mean ± SD operative time was 295 ± 94 min and blood loss was 600 ± 248 ml. Intraoperatively, duodenal perforation and ureteral injury were encountered in 1 and 2 patients respectively, and 8 patients required blood transfusion.

Postoperative Clavien–Dindo Grade I complications comprised fever (11 patients, 20.4%), pain managed with allowed analgesics (9 patients, 16.7%) and prolonged chylous lymphorrhea (3 patients, 5.6%). Grade II complications included blood transfusion (5 patients, 9.3%), wound infections treated with antibiotics (6 patients, 11.1%), respiratory infection (2 patients, 3.7%) and deep vein thrombosis (3 patients, 5.6%). Regarding major complications, 5 patients (9.3%) developed wound dehiscence managed under local and general anesthesia (3 Grade IIIa and 2 IIb). No Grade IV or V complications occurred. Mean ± SD postoperative hospital stay was 8.5 ± 3.4 days (min 6, max 64 days).

Histology of resected masses revealed fibrosis/necrosis in 33 cases (61.1%), mature teratoma in 15 cases (27.8%), and viable non-seminoma/seminoma in 6 cases (11.1%). With a median follow-up of 14 months (min 4, max 41 months), 53 patients had complete disease remission following RPLND, while one case with distant metastatic spread died, approximately 9 months postoperatively.

**Conclusions:** In accordance with current knowledge, our findings reveal that PC-RPLND can offer excellent disease control in selected patients, with acceptable rates of peri- and postoperative complications.

**P166**

**Additional surgical procedures in patients undergoing postchemotherapy retroperitoneal lymph node dissection for testicular cancer: A single center report**

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**Introduction & Objectives:** According to current literature, additional surgical procedures are required in at least 20% of patients subjected to Post-Chemotherapy Retroperitoneal Lymph Node Dissection (PC-RPLND) due to postchemotherapy desmoplastic reaction and incarceration of adjacent structures from residual masses. The current study aims to present the adjunctive to PC-RPLND surgical procedures performed in a group of testicular cancer patients.

**Material & Methods:** From 2009–2014, a total of 54 testicular patients underwent PC-RPLND in our department. A retrospective review of patients’ records was performed and demographic and clinicopathological parameters were obtained. Clavien–Dindo classification system was used to characterize postoperative complications that occurred.

**Results:** Of the 54 patients subjected to PC-RPLND, additional surgical procedures were required in 11 of them (20.4%). Two patients were diagnosed with seminomatous germ cell tumour and the remaining 9 patients had a diagnosis of non-seminoma, according to the histology of the orchectomy specimen. With regards to clinical stage of disease, 2 out of the 11 patients (18.2%) were classified as stage IIB, 3 patients (27.3%) as stage IIC, 4 patients (36.4%) as stage IIIB and 2 patients (18.2%) as stage IIIC.

Median age of patients was 29 years (minimum 21, maximum 38 years of age) and median largest diameter of retroperitoneal masses before RPLND was 9.1 cm. Full bilateral RPLND was performed in all 11 patients. Eight patients underwent standard RPLND, 2 patients were subjected to salvage RPLND and desperation RPLND was carried out in 1 patient. In total, 14 additional surgical procedures were performed and comprise inferior vena cava resection (2), left-sided nephrectomy (4), transureteroureterostomy (2), resection of hepatic metastases (2), ileal ureter replacement (1), vertebral resection (1), renal autotransplantation (1) and intraoperative radiofrequency ablation of hepatic lesions (1).

The median operative time required was 315 min and median blood loss was 640 ml. Intraoperatively, blood transfusion was required in 6 out of 11 patients (54.6%), with a median number of 4 packed red blood cells.

Postoperative Grade I complications included fever (5 patients), pain managed with allowed analgesics (7 patients) and prolonged chylous lymphorrhea (1 patient). Grade II complications included blood transfusion (3 patients), wound infection requiring antibiotics (2 patients) and deep vein thrombosis (1 patient). One patient developed wound dehiscence managed under general anesthesia (Grade IIb). No Grade IV or V complications took place. Renal
autotransplantation failed, due to renal vein thrombosis diagnosed on third postoperative day. Total median hospital stay after the procedure was 10 days (min 8, max 64 days). With a median follow-up of 12 months, all 11 patients had complete disease remission following RPLND.

**Conclusions:** In accordance with previous reports, our study shows that a significant number of testicular cancer patients with indications for PC-RPLND will require adjunctive surgical procedures, in an effort to achieve optimal disease control.
ESUI Oral Presentations

Imaging

**EO7**

Staging and restaging prostate cancer with Ga-68 PSMA PET-CT: Initial results of a contemporary cohort

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Introduction & Objectives: Prostate specific membrane antigen, given its favorable molecular characteristics, is an ideal target for prostate cancer-specific nuclear imaging. In this study, we aimed to assess the utility of Ga-68 PSMA PET-CT in prostate cancer with regard to staging prior to definitive treatment and restaging after various treatment modalities.

Material & Methods: Charts of the patients who were either staged or restaged with Ga-68 PSMA PET-CT between February 2014 and March 2015 in a private referral center were retrospectively reviewed. A total of 69 studies conducted in 64 patients (staging = 28, restaging = 41) were evaluated. Clinical characteristics, imaging findings and tailored treatment decisions were reported.

Results: Median patient age and serum PSA level at the time of imaging was 68 years, 6.6 ng/ml and 65.5 years, 1.6 ng/ml, respectively in the staging and restaging groups. In the staging group, 11 patients were found to have metastatic PSMA accumulations and the majority (10/11) were scheduled for antiandrogenetic treatment. The remaining patient with limited pelvic lymphatic spread was operated on and histopathological findings confirmed PSMA PET-CT results. The smallest extraprostatic PSMA positive lesion was measuring 3 mm in its greatest dimension. Out of 17 metastasis-free patients, 13 underwent radical prostatectomy (including bilateral pelvic lymphadenectomy) and histopathological results were consistent with PSMA based imaging findings in 12 of them (92%). In the restaging group, Ga-68 PSMA PET-CT was able to detect prostatic and/or extraprostatic PSMA-positive recurrent and/or metastatic lesions in all patients with the smallest positive lesion measuring 3 mm in its greatest dimension. In the post-RP and post-RT settings; the lowest serum PSA values that were associated with a demonstrable PSMA-positive lesion was 0.08 and 3 ng/ml, respectively. Regarding those patients who have undergone RP and received additional treatments, the lowest serum PSA value that was associated with an identifiable PSMA-positive lesion was 0.3 ng/ml. In 5 of the restaged patients, histopathological examination of the biopsy samples confirmed the presence of prostate cancer.

Prostatic PSMA positive lesions of the treatment-naive patients with Gleason ≥8 prostate cancer had higher mean SUVmax value than that calculated for patients with Gleason ≤7 disease (12.3±6.4 vs. 4.03±1.06, respectively, p=0.0001). Mean hepatic SUVmax values of these high-grade and low-grade patients were similar (5.4±1.3 vs. 5.7±1.7, respectively, p=0.76).

To sum up; histopathological correlation of Ga-68 PSMA PET-CT results is available in 19 patients (29.6%). In all of these patients, except one in whom PSMA PET-CT failed to demonstrate lymph node metastasis of primary disease, histopathological findings were consistent with the nuclear imaging results.

Conclusions: Ga-68 PSMA PET-CT is a promising imaging modality that can be used for staging prostate cancer and unrevealing the cause of post-treatment PSA elevations. Further studies are needed to justify its utility in the management of prostate cancer.

**EO8**

MRI can reduce the number of prostate biopsies after previous confirmatory biopsy in men on active surveillance for low-grade prostate cancer

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Introduction & Objectives: MRI can reduce the number of prostate biopsies after previous confirmatory biopsy in men on Active Surveillance (AS) are limited.

To compare outcomes of MRI + target biopsy (TBx) vs. TRUS-guided systematic biopsy (SBx) at 2nd surveillance biopsy after previous confirmatory biopsy. TBx of suspicious lesions (PI-RADS ≥3) was performed using the MRI–US fusion technique. 62 men (all participants in the PRIAS study; www.prias-project.org) who received 2nd surveillance SBx served as a control group. Outcomes of TBx and SBx were compared to assess the upgrading rates and potentially saved biopsy procedures when biopsying only those men with a positive MRI. Cox proportional hazard regression analysis was performed to assess whether receiving MRI was an independent predictor for upgrading, after correction for age and PSA.

Results: See the table. MRI+ TBx resulted in more Gleason score upgrading than SBx (27% vs. 8%). However, men who received MRI instead of SBx had higher PSA-levels both at diagnosis and at 2nd surveillance biopsy. After correction for the PSA-levels, receiving MRI was no independent predictor for upgrading;
HR = 1.39 (95% CI 0.16–3.3), p = 0.672. Although the PSA-levels and high-grade (Gleason score ≥3+4) PCa rate were higher in the MRI group, 27% of these men had a negative MRI and thus did not receive TBx.

<table>
<thead>
<tr>
<th>MRI + TBx</th>
<th>SRx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median (IQR)</td>
<td>67.5 (62.1–72.0)</td>
</tr>
<tr>
<td>Time between diagnosis and biopsy (years), median (IQR)</td>
<td>3.8 (2.8–5.6)</td>
</tr>
<tr>
<td>PSA at diagnosis (ng/ml), median (IQR)</td>
<td>72.4 (48.9–93.3)</td>
</tr>
<tr>
<td>PSA at biopsy (ng/ml), median (IQR)</td>
<td>10.3 (5.9–15.0)</td>
</tr>
</tbody>
</table>

**Outcome 2nd surveillance biopsy**

MRI not suspicious for PCa | No PCa in biopsy | 8 (27%) | 6 (20%) |
| Gleason score = 3+3 PCa in biopsy | 8 (27%) | 33 (53%) |
| Gleason score ≥3+4 PCa in biopsy | 8 (27%) | 5 (8%) |
| Total no. of patients | 30 (100%) | 62 (100%) |

**Conclusions:** A larger sample size and follow-up data are needed to confirm these preliminary results: Performing a MRI at 2nd surveillance biopsy could save ~30% of prostate biopsy procedures without compromising the identification of disease progression.

**EO9**

**Targeted dual-modality imaging in renal cell carcinoma: An ex vivo kidney perfusion study**

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**Introduction & Objectives:** Intraoperative imaging can provide valuable information about tumour localization and may improve complete tumour resection. Girentuximab may be used as a tumour-targeting agent to image clear cell renal cell carcinoma (ccRCC). It targets carbonic anhydrase IX (CAIX), which is expressed in 95% of ccRCC. Labeled with both a near-infrared fluorescent dye (IRdye 800CW) and a radionuclide ([Indium–111]), girentuximab can be used to perform intraoperative dual-modality imaging. This study aimed to assess the feasibility of dual-modality imaging in ccRCC using ex vivo perfusion of human tumorous kidneys with dual-labeled girentuximab.

**Material & Methods:** After informed consent six kidneys were obtained from patients who underwent a radical tumour nephrectomy. After nephrectomy the renal artery was connected to a pump via a catheter. Five kidneys were perfused during 10–15 h with 111In-girentuximab-IRdye 800CW (1.2 mg, 3.6–5.2 MBq) in 350 ml Ringer’s lactate (4°C). To demonstrate selective binding of girentuximab one specimen was perfused with a mixture of two dual-labeled antibodies; 111In-girentuximab-IRdye 800CW and an irrelevant control antibody (IgG) 125I-IgG-IRdye 800CW. Next, the kidneys were perfused with Ringer’s lactate (2.5–4 h) to wash out unbound antibody. Then, a 5-mm thick slice of the kidney was analyzed by autoradiography and fluorescence imaging. Antibody accumulation was determined quantitatively by measuring the activity in 1 cm³ cubes of tumour and normal tissue in a gamma counter. These were subsequently analyzed (immuno)histochemically.

**Results:** Accumulation of dual-labeled girentuximab in tumour tissue was clearly visualized by autoradiography and fluorescence imaging. The match between the radioactive/fluorescent signal and CAIX expression was excellent. Maximum tumour uptake of girentuximab was 0.33% of the injected dose per gram (mean 0.12 %ID/g) versus 0.04 %ID/g (mean 0.02 %ID/g) in normal kidney tissue. Perfusion with the mixture of two dual-labeled antibodies resulted in a mean tumour uptake of 0.01 %ID/g of 125I-IgG-IRdye 800CW, which was significantly lower than the uptake of 111In-girentuximab-IRdye 800CW (0.08 %ID/g, p < 0.05).

**Conclusions:** Dual-labeled girentuximab accumulated specifically in ccRCC tissue indicating the feasibility of dual-modality imaging to detect ccRCC intraoperatively. A clinical study to evaluate intraoperative dual-modality imaging in ccRCC patients has been initiated.

**EO10**

**Percutaneous 3T MR-guided cryoablation of small renal masses: An initial experience**

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**Introduction & Objectives:** MR image-guidance offers good intra procedural monitoring capabilities and enables near real time ice ball visualization during cryoablation. Thereby it may improve protection of surrounding anatomical structures and might improve technical and oncological outcomes. Our aim is to describe our approach to percutaneous MR-guided cryoablation of small renal masses in a 3T MRI environment and to evaluate procedural safety, needle visibility, needle artifacts and ice ball visualization.

**Material & Methods:** Patients unfit for surgery with a T1a kidney tumor were treated with percutaneous cryoablation. Exclusion criteria were contraindications to undergo MR imaging. A Siemens wide bore 3T MR system, Galil MRI Seednet Cryoablation system and 17G MRI-compatible cryoneedles were used. After general anesthesia was applied, biopsies were taken and the cryoneedles were inserted under ultrasound guidance. Position of the cryoneedles was verified under MR image guidance and adjusted if necessary. To protect anatomical structures such as the ureter and colon from freezing, dissection was performed with infusion of warm saline if necessary. Two freeze-thaw cycles were applied. Visualization of the needle tract and tip without disturbing artifacts was optimized by adjusting the orientation of the plane and field of view before freezing. Ice ball formation was continuously monitored with near real-time MR imaging using T1 VIBE or T2 Haste sequences.

Conclusions: First experience in 4 patients on 3T MRI showed good visualization of the needles with minimal artifacts. The extent of the ice ball and surrounding anatomical structures were clearly
visualized during the procedure. All procedures were technically successful and no significant complications or loss of kidney function were observed.

**Conclusions:** We present a feasible and safe approach for percutaneous MR-guided cryoablation in patients with small renal masses in a 3T MRI environment. Intraprocedural imaging showed good visualization of the critical anatomical structures, ice ball formation and needles without significant artifacts.
ESUI Unmoderated Poster Presentations

Imaging

EP167  Radiographic features of the main granulomatous disease with involvement of the genitourinary system. Differential diagnosis and case presentation

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Introduction & Objectives: Granulomas are inflammatory character nodularles formations, consisting essentially of macrophages. There are several diseases that still under study mechanisms granulomatous reactions occur at different locations, including the genitourinary system, constituting a diagnostic challenge to the urologist. Describe through clinical cases presented to our urology department, radiological findings in granulomatous diseases that tend to generate diagnostic uncertainty with consequent clinical implication.

Material & Methods: Systematic study by plain radiography, ultrasound, computed tomography and nuclear magnetic resonance cases presented in our service as the testicular sarcoidosis and genitourinary tuberculosis.

Results: Sarcoidosis is a chronic disease of unknown etiology, characterized by noncaseating epithelioid granulomas in multiple organs and tissues. Bilateral hilar lymphadenopathy is the most common radiographic finding. 30% of patients present with extrapulmonary disease, including the genitourinary system. Injuries to testicular level is a real challenge differential between tumour masses. In the case presented objective as testicular lesions are characteristic, multiple hypoechoic and small. When the masses are in patients with confirmed sarcoidosis, sarcoidosis testicular possible should always be considered, because it can prevent unnecessary orchietomies. Genitourinary tuberculosis is an important but unusual location, but is the second form of extrapulmonary tuberculosis. Diagnosis is difficult and often delayed because tuberculosis can mimic many other diseases. Imaging studies are very useful to detect the presence of tuberculosis and to monitor response to treatment. This review illustrates the radiological findings in genitourinary tuberculosis in patients with laboratory confirmation of the disease.

Conclusions: Granulomatous disease with genitourinary involvement are rare, and can simulate many of the diseases affecting the urinary tract, so it will be a diagnostic challenge for the urologist, which will require knowledge of the key findings in tests image of these institutions.

EP168  Evaluation of chemotherapy response in seminomas

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Introduction & Objectives: Metastatic seminoma is the paradigm of a curable cancer. Pure seminomas stages II with bulky disease and stages III are generally treated with platinum-containing chemotherapy. BEP (bleomycin, etoposide and cisplatin) is the standard treatment. After chemotherapy, patients are evaluated with a CT scan. If there is found a residual tumour >3cm, a PET scan is recommended. A negative PET warrants follow-up. In a positive PET lesions must be regarded as harbouring viable tumour and should be resected, if technically possible.

We want to evaluate the radiological responses to chemotherapy in pure seminomas, how residual mass dimension influenced our clinical decisions and the number of unnecessary procedures due to false-positive results on PET.

Material & Methods: This retrospective study involved two Centers: Institut Català d’Oncologia – L’Hospitalet and Hospital de Santa Maria. The authors reviewed patients’ files with pure seminoma stages II and III treated with BEP or EP from 1996 to 2014 to evaluate the type of responses to chemotherapy and the clinical decisions in front of residual masses.

Results: Fifty patients with pure seminoma stages II and III were eligible for evaluation. The median age was 36 years old (range 22–54). The median follow-up was 4.3 years. All patients had primary testicular seminoma except two that had primary mediastinal disease. Forty three patients had stage II and seven had stage III disease. All patients belong to good IGCCC prognostic group except two. Thirty four patients had metastatic seminoma is the paradigm of a curable cancer. Pure seminomas stages II and III are generally treated with platinum-containing chemotherapy. BEP (bleomycin, etoposide and cisplatin) is the standard treatment. After chemotherapy, patients are evaluated with a CT scan. If there is found a residual tumour >3cm, a PET scan is recommended. A negative PET warrants follow-up. In a positive PET lesions must be regarded as harbouring viable tumour and should be resected, if technically possible.

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Conclusions: Patients with metastatic seminoma treated with chemotherapy have a high percentage of cure. PET is actually the better tool to guide clinical management of residual tumors, particularly for surveillance. In our population there was no benefit to do a PET for lesions <3 cm. Due to some false-positive PET results, some patients were overtreated. It is important to optimize the selection of patients for surgery.

EP169
MpMRI-Histopathologic correlation of normal, benign and malignant conditions of the prostate
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Introduction & Objectives: To correlate the histopathologic myriad of normal, benign and malignant conditions with corresponding findings on multiparametric magnetic resonance imaging (mpMRI).

Material & Methods: Fifty-six whole-mount histopathological specimens of ten randomly selected patients were matched with corresponding transverse mpMRI slices performed at a 3.0 Tesla scanner without endorectal coil. The mpMRI consisted of T2-weighted imaging (T2-WI), diffusion-weighted imaging (DWI), dynamic contrast-enhanced imaging (DCE) and Magnetic Resonance Spectroscopic Imaging (MRSI).

Results: In each prostate, a wide range of histopathological conditions was observed. In the peripheral zone, normal prostate glands were iso-intense on T2-WI, while high signal intensity areas represented cystic atrophy. Adenosin, high-grade prostatic intra-epithelial neoplasia and post-atrophic hyperplasia were mimickers of well-differentiated prostate cancer (PrCa) and all showed similar mpMRI characteristics. Fibromuscular hyperplasia, fibromuscular stroma, and poorly differentiated PrCa showed a similar appearance on T2-WI and DCE.

Conclusions: Most histopathologically normal, benign and malignant conditions in the prostate showed consistent but overlapping characteristics on mpMRI. Understanding the main concepts of this mpMRI-histopathological correlation may increase the diagnostic confidence in reporting mpMRI.

EP170
Aberrant metastatic pathways in prostate cancer found using PET sentinel lymph node imaging
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Introduction & Objectives: We assessed the possibility of using a novel PET/CT technique to identify sentinel lymph nodes in men with prostate cancer. Sentinel lymph node imaging using single-photon emission computed tomography (SPECT) improves the yield of positive lymph nodes from pelvic lymph node dissection for prostate cancer. This SPECT imaging shows that non-traditional lymphatic pathways are more common than not. Furthermore, given the predisposition of metastases to bone, in particular pelvic and lower vertebral bones, we hypothesised that the dynamic, 3D and highly sensitive nature of PET would enable the evaluation of previously unidentified channels of non-lymphatic metastatic spread.

Material & Methods: This pilot study of a novel imaging technique recruited patients who required implantation of gold fiducials for definitive prostate cancer radiation therapy. Participants underwent ultrasound guided transperineal intra-prostatic injection of a PET tracer (gallium-68 nanocolloid) at time of placement of gold fiducials. After recovering from anaesthetic they underwent PET/CT imaging. Participation in the study did not affect their course of cancer management. Between 8 and 23 participants were required to be confident of the technique's ability to identify sentinel lymph nodes. The first 3 participants underwent standard technetium SPECT imaging in order to optimise technique prior to use of the PET tracer.

Results: Five men were administered the gallium-68 PET tracer and 3 received standard technetium SPECT imaging. Sentinel lymph node identification was successfully performed in all eight participants, allowing completion of the pilot study as per protocol. Unexpected potential pathways for transit of malignant cells as well as expected regional drainage pathways were discovered. Rapid tracer drainage to pelvic bone, perivesical, mesorectal, inguinal and Virchow's nodes was identified. Prevalence of both aberrant and non-lymphatic pathways of spread could be further investigated with this technique.

EP171
Rates of bladder, gastrointestinal toxicity and erectile dysfunction following radical radiotherapy for localised/locally advanced prostate cancer
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Introduction & Objectives: The impact of advances in prostate cancer radiotherapy planning and delivery, as well as image guided radiotherapy (IGRT) techniques on radiotherapy induced toxicity needs to be monitored. The aim of this small prospective study is to add data that will give a better understanding of radiotherapy side-effects seen in the general population outside of clinical trials. The data was collected prospectively initially in a doctor led clinic and then in the urology specialist nurse led service for patients who started radiotherapy during the years 2008–2011.

Material & Methods: 38 patients were identified in our District General Hospital who received radical external beam radiotherapy for their localised/locally advanced prostate cancer. These men are followed up for a total of 5 years and their late Bladder/Erectile dysfunction/gastrointestinal side effects were prospectively assessed by the use of a modified EORTC/ RTOG score (modified for ease of clinical use). All grades of side effects were evaluated.

Results: Of the 38 patients, 32 (84%) received in total 74 Gray in 37 fractions over seven and a half weeks. The rest received varying amounts depending on patient factors not assessed in this study. Median age: 73.5 years (range 60–80). Median follow-up: 36 months (range 16.5 to 60 months). Gastrointestinal side effects were reported as follows: 6 (16%) patients reported grade 2 symptoms according to the modified EORTC/RTOG scores, grade 3 toxicity was reported in 1 patient (2%), no patients had grade 4 toxicity. The median time of onset was 10.5 months (range 1.5–48 months). Bladder side effects were reported as follows: 9 patients (23%) had grade 2 toxicity with no reported grade 3 or 4 bladder toxicity. Median time to onset: 3 months (range 1.5–22.5 months). With regards to erectile dysfunction (ED) this was reported in 36 patients (2 had no data). A total of 14 patients (39%) had pre-existing problems and/or did not want to pursue treatment for this. 10 (28%) patients needed pharmaceutical support to achieve erections and 2 (5%) had grade 4 ED.
Conclusions: This prospective study has shown an acceptable rate of toxicity after radical radiotherapy. These assessments will continue to form part of our follow-up routine and we intend to continue to collect prospective data to assess if the introduction of intensity modulated radiotherapy and advanced IGRT techniques in recent years lead to reduced radiotherapy toxicity in this group.

EP172
Assessment of the distribution of intraprostatic antibiotic injections in chronic prostatitis using three-dimensional ultrasound (3D TRUS) – nine years’ experience
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Introduction & Objectives: Patients suffering from chronic prostatitis, particularly with acute and a severe pain not resolving after oral treatment, may be treated with the administration of intraprostatic antibiotic. An equal drug distribution within the whole prostate gland especially in the central zone is therapeutically desirable to obtain durable effects.

The aim of this study is to evaluate of the distribution of antibiotic administered in to the prostate gland in chronic prostatitis using three-dimensional ultrasound (3D TRUS).

Material & Methods: In the period of 01.01.2006 to 30.06.2015, intraprostatic antibiotic injection was performed in 36 patients. Indication for such treatment was persistent pain unrelieved after oral drug administration in chronic exacerbated prostatitis. 38 injections were performed – one single injection in 35 patients and 3 injections in one patient at 2 and 3 months interval. Age ranged from 24 to 68 years. Average age was 52.

Gentamycin (31 times), tazocin (4 times), augmentin (twice), ciprofloxacin (once) were administered in to the prostate according to bacteriogram results obtained from seminal cultures. All the injections were performed under transrectal ultrasound control (TRUS). Prostate images acquisition in transversal cross sections was achieved after classic TRUS execution. Prostate configuration has been analyzed and planned for injection after 3D USG. USG transducer was used to observe prostate in transversal and vertical cross-sections. Injectable drugs were given to each lobe in a precise regular and symmetrical manner. 3D USG images were achieved after each injection with evaluation of drug distribution in both lobes.

Results: 3D USG allows for an accurate planning of injectable drugs administration and evaluation of distribution in the prostate gland. The success of the local application of drugs depended on drug distribution assessed by 3D ultrasound evaluation. Pain complaints had relieved after single injection in 35 out of 36 patients. One patient needed 3 injections to gain good therapeutic effect.

Conclusions: 3D USG could be a valuable supplement for classic USG examination to precisely evaluate drug distribution and localization after intraprostatic injection. Besides, it permits an exact drug distribution which can lead to therapeutic successes.

EP173
Diagnoses and monitoring of disease course of the induration penis plastica using three dimensional ultrasound examination – Nine years’ experience
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Introduction & Objectives: Peyronie’s disease is characterized by formation of hardened scar and fibrous tissue in the tunica albuginea, septum and corpora cavernosa of the penis. Its typical symptoms are the painful bend during erection, which makes sexual intercourse difficult and palpable plaque or tough “cord” on the dorsal side of the penis. Proper evaluation of the plaque's location and size is important in the choice of treatment method and in the evaluation of the effects of instituted treatment. 3D ultrasound transducers enable to obtain three-dimensional images and make the evaluation of the examined organ more accurate.

The aim of this study was to present the examination methods, indications and advantages of three-dimensional ultrasound in the diagnosis of induratio penis plastica (Peyronie’s disease) and assessment of the effects of treatment.

Material & Methods: 3D ultrasound scanning was performed in twelve patients with Peyronie’s disease with palpable plaques in the tunica albuginea of the penis. The scanning was carried out with a linear transducer (ultrasonic wave frequency of 12 MHz) positioned transversely to the long axis of the penis and then moved from the root of the penis towards the glans penis. During movement of the transducer, single ultrasound images are obtained and arranged to give an appearance of a three-dimensional image.

Results: We obtained the ultrasound images, encoded as “volumetric units”, or voxels, and arranged to form a cube, which was later computer-processed, using a specially designed computer program. In addition to traditional longitudinal and transverse views, it enabled to obtain also a coronal view. In patients with Peyronie’s disease, this third view is of great importance since it allows for visualization of the whole plaque. Careful image analysis performed after the examination (not in the patient’s presence) allowed to identify other, smaller plaques which were not observed prior to examination.

Conclusions:
1. 3D ultrasound diagnosis allows for more accurate evaluation of pathologic changes in the tunica albuginea of the penis in Peyronie’s disease.
2. Final evaluation involving analysis of obtained images is done after the examination and not in the patient’s presence.
3. Examination time is shortened when compared with two-dimensional ultrasound.

EP174
Assessment of the severity of the traumatic injury of the penis tunica albuginea (fractura penis) using three dimensional ultrasonography (USG 3D) – nine years’ experience
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Introduction & Objectives: Clinical symptoms of penile fracture are very characteristic and include: severe pain during trauma, the sound of cracking stick, ecchymosis and saxophone-like bending of the penis. Ultrasonographic examination performed shortly prior to a surgical procedure allows the specialist to evaluate the size and location of hematoma as well as the extent of damage to the albuginea. 3D ultrasonography reduces the duration of examination (acquisition time only) and allows for more accurate evaluation of the location of damage to the albuginea (analysis of voxels within a cube acquired during data acquisition).

The objective of this study is to present the method of examination using a high frequency linear probe and 3D ultrasonography software for evaluation of the extent and location of damage to the albuginea and the size of hematoma.

Material & Methods: The study includes examination of nine patients admitted to the Clinic with the diagnosis of penile fracture and qualified for surgery. Indication for the examination was penile ecchymosis, significant bending of the penis, pain and cracking sound heard during the trauma. The examination was performed using a linear probe with 12 MHz frequency of ultrasound wave which was set laterally to the longer axis of
2. The final evaluation, i.e. analysis of the acquired images, was performed after the examination has been completed and does not require patient participation which significantly reduces the duration of examination, as compared to the classical ultrasonography.

Conclusions:
1. 3D ultrasonography is a valuable examination in addition to the traditional two-dimensional ultrasonic examination of the penis. The new tool for ultrasonic diagnostic facilitates more accurate evaluation of the location and extent of damage to the albuginea.
2. The final evaluation, i.e. analysis of the acquired images, is performed after the examination has been completed and does not require patient participation which significantly reduces the duration of examination, as compared to the classical ultrasonography.

Material & Methods: Twelve investigations estimating urinary bladder wall thickness at 4 patients were performed. Each patient urinated prior to the study and approached to the study about 15 minutes after voiding the bladder. The investigation was executed using the transvaginal 10MHz USG probe which gives the image of whole urinary bladder. In order to obtain reliable results of measurements, the bladder should not contain more than 30 ml of urine during the study. The assessment of the volume of urine in the urinary bladder was performed in the first stage of the investigation. The width was measured in maximum transverse dimension and the height and length of the urinary bladder were measured in the longitudinal cross section. The result can be obtained using the pattern: H × W × L × 0.7. The coefficient 0.7 allows for more exact calculations in a slightly filled bladder than universally applied coefficient 0.56 (π/6).

Results: 3D bladder wall images were obtained. In all examinations, the bladder wall was well visible, well bounded from surroundings. Precisely defined places for measuring bladder wall thickness made the investigations comparable and repeatable.

Conclusions:
1. TVUS 3D is a valuable supplement to the classic USG 2D investigation of the urinary bladder wall.
2. Correct preparation of the patient is an essential condition for correct bladder wall thickness measurement.

EP177
Tumour size in MRI and percentage of cancer in biopsy are independent predictors of side-specific pathologic T3 prostate cancer
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Introduction & Objectives: Multiparametric magnetic resonance (MP-MRI) is considered the most accurate imaging modality for detecting prostate cancer. Preoperative staging is one of its potential applications. Information on the localization and extension of the tumour may influence decision which neurovascular bundle should be preserved. Extraprostatic extension (ECE), however, is often difficult to visualize. The aim of this study was to find if MP-MRI is useful in predicting side-specific prostate cancer ECE or seminal vesicular invasion (SVI).

Material & Methods: This prospective study covers first two years after implementation of prostate MP-MRI in our centre. The consecutive group of 70 patients with prostate cancer, who underwent MP-MRI followed by radical prostatectomy was enrolled. 1.5 T MR scanner and endorectal coil were used to acquire images (T2-weighted, diffusion-weighted and dynamic contrast-enhanced). One radiologist assessed all imaging studies and scored lesions using a 5-point Likert scale. The following parameters were considered as potential predictors of stage T3 disease: Digital rectal examination, PSA and TRUS results, Gleason score, percentage of cancer in biopsy, presence and size of Likert scale score 4 or 5 lesions in MP-MRI. Analysis was performed for each side of the prostate separately in order to mimic decision on nerve-sparing. ROC analysis was used to find best cut-off values. Cut-off value of >15% of cancer in biopsy was chosen according to literature overview. Independent predictors of side-specific ECE or SVI were identified by multivariate logistic regression analysis.

Results: Mean age of 70 patients was 66. ECE or SVI was found in 35 patients (50%) and in 45 prostate sides (32%). Analysis revealed two independent predictors of side-specific ECE or SVI: Percentage of cancer in biopsy >15% (odds ratio 2.0; 95% confidence interval 1.4–3.0; P = 0.001) and maximal dimension of MRI-detected lesion (score 4 or 5) >15 mm (odds ratio 1.8; 95% confidence interval 1.2–2.9; P = 0.011). The model consisting of >15% cancer in biopsy
specimens from one lobe or >15 mm lesion in MP-MRI was characterized by 75% sensitivity, 72% specificity, 56% positive predictive value and 86% negative predictive value (AUC=0.736). For >15% cancer in biopsy AUC was 0.691 and for large lesions in MRI AUC was 0.643. Model accuracy was independent of study team experience: Similar characteristics were achieved in the first and in the second half of the group.

**Conclusions:** MRI-detected lesion size >15 mm is an independent predictor of ECE or SVI. This variable significantly increases ability of biopsy parameters to predict prostate cancer stage, which may affect decision on preserving neurovascular bundles. Extensive experience in interpreting prostate MRI is not required to use this predictor.

**EP178**

**Diagnostic value of (68)Ga-PSMA PET/CT in biochemical recurrence of prostate carcinoma with low PSA levels**

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**Introduction & Objectives:** 68Ga-DKFZ-11 (68Ga-PSMA) has been suggested as a novel tracer for detecting of PCa relapses and metastases. However there is a limited number of publications about the timing of PSMA PET/CT scan. The aim of the study is to evaluate the diagnostic value of PSMA PET/CT in the diagnosis of recurrent prostate cancer with low PSA levels.

**Material & Methods:** We performed a retrospective analysis in patients who underwent PSMA PET/CT from November 2013 to December 2014 in our department. 53 out of 178 patients who had rising PSA levels (still lower than 5 ng/ml), and did not have known metastasis were included in this study.

**Results:** Patients had an average PSA of 1.41 ng/ml. A total of 31 patients (58%) showed at least one extraprostatic or prostatic lesions. Intense pathologic radiotracer uptake was observed in 15 patients (28%) at the site of primary tumor. Lymph node metastases were detected in 19 patients (36%) and bone metastases were detected in 8 patients (15%). A PET positivity rate of 31% (n=4), 54% (n=13) and 88% (n=14) observed in patients with PSA level of <0.2, 0.2–2 and 2–5 ng/ml respectively. Those with PSA level PSA <0.2, 0.2–2 and 2–5 ng/ml had 8% (n=1), 21% (n=5), 56% (n=9) local recurrence 15% (n=2), 42% (n=10), 44% (n=7) lymph node metastasis and 15% (n=2), 8% (n=2), 25% (n=4) bone metastasis. A positive correlation observed between positivity rate and gleason scores (15% for Gleason 6, 55% for Gleason 7, 75% for Gleason 8 and 77% for Gleason 9). PSMA PET/CT positivity's confirmed with biopsy (n=3), follow-up (n=26) and conventional imaging studies at the time of the PET/CT (n=11) or during follow up (n=13). According to patient-based analysis of 44 cases, 57% (n=25) of patients had true positive, 23% (n=10) of patients had true negative, 2% (n=1) patient had false positive, 18% (n=8) of patients had false negative findings which are leading to a sensitivity of 58.1% (95%CI: 42.1–72.9) specificity of 90% (95%CI: 48.6–98.5%). Within the patients who had PSA levels from 0.2 to 5, the sensitivity was 79.3% (95%CI: 60–91.9%).

**Conclusions:** PET/CT with 68Ga-PSMA is a valuable tool for assessing recurrence of PCa with a high sensitivity (79.3%) within the patients who has PSA levels between 0.2–5 ng/ml. Additionally PSMA PET/CT can be used in patients with very low (<0.2 ng/ml) but increasing PSA levels, which in many cases may influence the clinical management.
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